(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF] Sent: 4/30/2020 5:24:59 PM To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd] CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc] Subject: RE: Gilead and ACTIV TX-Clinical Master Protocol Subgroup Meeting #7 Excellent From: Lane, Cliff (NIH/NIAID) [E] Sent: Thursday, April 30, 2020 12:51 PM To: Wholley, David (FNIH) [T] b6 Collins, Francis (NIH/OD) [E] Cc: Tabak, Lawrence (NIH/OD) [E] b6 ; Freire, Maria (FNIH) [T] { Subject: Gilead and ACTIV TX-Clinical Master Protocol Subgroup Meeting #7 I received an email yesterday (prior to the press release) from a relatively senior scientist that Gilead has re-considered and would like to be part of ACTIV. I was going to mention it on the call this afternoon. I think having them as part of ACTIV – given they have a strong track-record and likely the first directly acting anti-viral - would be good. Cliff From: "Wholley, David (FNIH) [T]" [Date: Thursday, April 30, 2020 at 10:18 AM "Lane, Cliff (NIH/NIAID) [E]" To: "Collins, Francis (NIH/OD) [E]" b6 b6 Subject: FW: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7 FYI, something to think about. From: Bozzette, Sam (NIH/NCATS) [E] Sent: Thursday, April 30, 2020 9:19 AM To: Adam, Stacey (FNIH) [T] ; Collins, Sylva ; Butterton, Joan (FDA/CDER) ; Judy Currier [] De Claro, R. Angelo (FDA/CDER) b₆ b6 ; Keith Gottesdiener Mark Eisner LaVange, Lisa M Eric Hughes b6 Elliott Levy Sandeep Menon ; Amanda Peppercorn ; Proschan, Michael (NIH/NIAID) [E] Read, Sarah b₆ }; Amanda Peppercorn [Price, Dionne (NIH/NIAID) [E] (FDA/CDER) Rubin, Daniel B. (FDA/CDER) Shen, Yuan Li b6 Farley, John (FDA/CDER) (FDA/CDER) Goff, David (NIH/NHLBI) Vincent, Michael [E] [b6 Cc: Mary Biggs Macone, Erin Demarcus b6 Tountas, Karen (FNIH) [T]]; Wachtel, Jonathan < Elizabeth Kim b6 Parker, Ashley (NIH/OD) [E] Butcher, Tina i; Wholley, David (FNIH) [T] b6 Melencio, Cheryl (FNIH) [T] Wung, Peter /US ; Qashu, Felicia (NIH/OD) [E]

Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

From:

b6 Stra	atton, Benjamin < <u>bstra</u>	tton@DELOITTE.com>		
Subject: Re: ACTIV TX-Clinical				
Good morning all:				
It would seem that our active than later - or have we alread			get in the queue v	vith Gilead sooner rather
S				
	,	······································		
From: "Adam, Stacey (FNIH) [Date: Thursday, April 23, 202	0 -+ 0.31.00 DM	i i i		
To: "Bozzette, Sam (NIH/NCA	TS) [E]" b6	"Butterton	, Joan"	b6] "De Claro, R. [], "Keith Gottesdiener" a M"
To: "Bozzette, Sam (NIH/NCA "Collins, Sylva (FDA/CDER)" Angelo (FDA/CDER)"	b6	"Judy Currier"	b6	, "De Claro, R.
Angelo (FDA/CDER)"	b6	, "Mark Eisner"	þ6	¨;, "Keith Gottesdiener"
b6	, "Eric Hughes"	b6	, "LaVange, Lis	a M"
b6 , "Elli	iott Levy" b6	"Sandeep N	/lenon" {	b6
"Amanda Peppercorn"	b6	"Proschan, Micl	nael (NIH/NIAID) [E]"
b6 , , ,	'Read, Sarah (NIH/NIAI	D) [E]" b6	, "Amand	a Peppercorn"
b6	, "Price, Dionne	(FDA/CDER)"	b6	""] "Rubin, Daniel B.
(FDA/CDER)"	, "Shen, Yı	uan Li (FDA/CDER)"	b6	, "Farley, John
(FDA/CDER)" b6	'Goff, Dav	D) [E]" b6 (FDA/CDER)" [uan Li (FDA/CDER)" rid (NIH/NHLBI) [E]" [b6	, "Vincent, Michael"
b6		, , , , , , , , , , , , , , , , , , , ,		,
Cc: "Mary Biggs" <	b6 "Demar	cus" b6	. "Macc	one, Erin"
b6 "Toun	ntas, Karen (FNIH) [T]"	b6	' 'Wachtel, Jonatha	n" [^]
l "E	ntas, Karen (FNIH) [T]"[lizabeth Kim" [b6 "Parker	. Ashlev (NIH/OD)	[E]"
b6 '"B	utcher. Tina"	h6 '. "V	Vholley, David (FN	IH) [T]"
b6 "Mele	ncio. Chervl (FNIH) [T]"	5 h6	"¡"Wung, Peter /l	
b6	utcher, Tina"[utcher, Tina"[ncio, Cheryl (FNIH) [T]" "Qashu, Felicia (NIH/OI	D) [E]" b6		n, Benjamin"
Subject: RE: ACTIV TX-Clinical	Master Protocol Suba	roup Meeting #7		
Subject. RE. ACTIV TA-CIIIICAI	iviastei Frotocol Subg	roup weeting #7		
Dear TX-Clinical Master Proto	col Subgroup,			
Please find attached the mate	erials for tomorrow's m	neeting.		
1. Agenda				
2. Slides for discussion to	·	•		
		_		t lines for COVID. This may
be a useful resource i	in selecting how to do	minimal data collectior	and trying to und	lerstand SOC.
Please let me know if you have	e questions or other th	hings you think would b	oe helpful for the g	group to review.
Thanks,				
Stacey				
Statey				
Stacey J. Adam, PhD				

Director, Cancer

Join Zoom Meeting

Research Partnerships
Direct: b6 | Mobile:

b6

b6

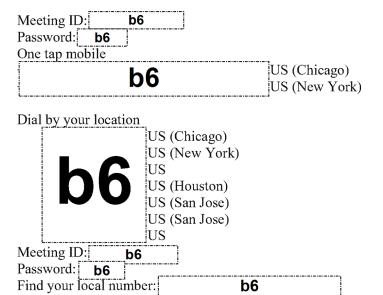
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	US (Houston)
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From:	Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]				
Sent:	4/30/2020 10:17:45 PM	1			
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	-		nange Administrative Group	8,8,	
			353e43d4463a04f7d74992f9	6ac-James.King.];	Kurilla, Michael
	(NIH/NCATS) [E] [/o=Ex	changeLabs/ou=Excha	nge Administrative Group	-	·
	(FYDIBOHF23SPDLT)/cn	=Recipients/cn=dc4e8	5061e3943b9b8ad3f426727	861f-mkurilla]; Na	ayak, Seema (NIH/NIAID)
	[E] [/o=ExchangeLabs/o				
			e6848004578b5bf9c808eca	8f6f-nayaksu]; Par	ker, Ashley (NIH/OD) [E]
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	•		244466140faa95aaaafe06ek	od70-parkeras]; Pa	ayton, Manizhe
		-	ge Administrative Group		
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		_	:3ebfcf48879f92169bd7644	29-lanet Woods	· Oashu Felicia (NIH/OD)
	[E] [/o=ExchangeLabs/o			ez 9-Janiet. Woodcj	, Qashu, Felicia (Mili/OD)
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	[marganderson@deloit		i]; ivie	lencio, Cheryl (FNIH) [T]
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	Heaton, Penny		; James, Stephanie (FNIH) [T		
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	Rose b6		i, Joseph (FNIH) [T] [/o=Exch		
	Group (FYDIBOHF23SPE	DLT)/cn=Recipients/cn:	=5001af52dc4a427ea3d34f1	e072f8cb7-menet	skijp]; Santos, Michael
	(FNIH) [T] [/o=Exchange	eLabs/ou=Exchange Ad	ministrative Group		
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	b6		olley, David (FNIH) [T] [/o=Ex		
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	b6	; Hamilton, Na	ncy b6	; Minnich	
į	b6	j; Katz, Rebecca (NI	H/NCATS) [E] [/o=ExchangeL	abs/ou=Exchange	Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Thomas, Ashley (FDA/CDER)
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Stratton, Benjamin
	[bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Victoria Davey [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da];
	Jintanat Ananworanich b6
Subject:	ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments:	Clinical Trial Capacity Working Group Meeting Agenda_05012020.pdf
Location:	b6
Start:	5/1/2020 1:00:00 PM
End:	5/1/2020 2:00:00 PM
Show Time As:	Tentative
_	
Recurrence:	Weekly every Tuesday and Friday from 9:00 AM to 10:00 AM
Required	Srinivasan, Badhri; Vincent, Mike; Stein, Peter (FDA/CDER); Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers,
Attendees:	Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Wachtel, Jonathan; Woodcock, Janet (FDA/CDER); Qashu, Felicia
Optional	Sizemore, Christine (NIH/FIC) [E]; Garner, Carlos; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin;
Attendees:	Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret;
	Carluccio, Dana; Cheryl (FNIH) Melencio [T] b6); Francis Collins; Gonzalez, Nina; Heaton, Penny;
	James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David
	(FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] b6 ; Thomas, Ashley (FDA/CDER); Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich
	Thomas, Asiney (10A) CDEN), Stratton, Benjamin, Tolman, Brett, Davey, Victoria, Jintanat Ananworanich
Dear Colleagu	ues, Agenda is attached. During this call we will hear the latest from the three sub-WGs – innovations,
	survey – which have been working very hard to move their activities forward quickly. Many thanks to all!
	have a bit of a brainstorming session about creating a 'dashboard' to use in analyzing survey results. Best
regards, Karei	1
ACTIV: Acce	elerating COVID-19 Therapeutic Interventions and Vaccines
Dear Clinical	Trial Capacity Working Group members,
In anticipation	n of this working group making rapid progress on identified action items and other activities, the co-chairs
	nat it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify
	and to determine next steps. We ask that you make every effort possible to join each of these meetings, but
	at at times you may have competing priorities. To place a hold on your calendar, please accept this meeting
	esponse; later you can decline an individual meeting if you have a conflict.
An agenda an	d other meeting materials, as needed, will be distributed prior to each call.

With best rega	ards,
Karen	
Karen H. Tou	ntas, PhD
	gram Manager
Foundation fo	r the National Institutes of Health
Join Zoom Mo	
	h6



From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	4/30/2020 11:04:32 PM
Го:	Eric Hughes b6 ; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa];
	Ruxandra Draghia-Akli b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel b6 ; Colvis,
	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John
	b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike
	b6 ; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];
	Vincent, Michael b6 ; Keith Gottesdiener b6 ; Elliott Levy
	b6 ; Wung, Peter /US b6 ; Koroshetz, Walter (NIH/NINDS) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner
	b6
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	Maria [rosalvarez@deloitte.com]; Salathin, Carla [
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	b6 Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject:	Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score
	Sheet (Agents Added)
Attachments:	lancet respiratory medicine.pdf; Immunohemostasis 2017 v032920.pdf; C19 Coagulopathy BLOOD 042720.pdf;
	Amgen - Otezla (Apremilast).pdf; Takeda - Takhzyro (Lanadelumab)- summary.pdf; Takeda - Firazyr (Icatibant) -
	summary.pdf; Lilly-Taltz.pdf; BMS - Orencia (Apatacept).pdf; Allergan - Cenicriviroc.pdf; EIDD-2801.pdf;
	Thromboiflammation Blood-2018-11-882993.full.pdf; Thromboinflammation JTH Ed 041720.pdf; cell research
	2020.pdf; compound list caco cells.pdf; preprints202004.0149.v1.pdf; Riva2020_REFRAME drug repositioning against
	SARS-CoV-2.pdf; ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-v2.xlsx

Dear TX-Clinical Agent Prioritization Subgroup,

I appreciate the candid and productive meeting that we had today. All your feedback is very helpful to refine our process for the next time.

For all of you working on scoring right now, please find attached a number of pieces of information that maybe helpful. Some if this some of your groups may have received before, however, I wanted to share it with the whole group for transparency and for having all of our reference data in one place. The information you will find attached is:

- 1. The summary spreadsheets for the agents in the host targeted category that have been added from the R&D Consortium group + 1 for b4 as it was requested. (one note, the group shared with us b4 is likely be tested in a few other trials, so that may need to be considered)
- 2. Articles on the evolving thrombosis issue that doctors are trying to deal with on the front lines. These were previously shared with the Symptomatic/Supportive therapy group.

- 3. An article relevant to immune modulator use in COVID-19.
- 4. Articles for the Antiviral group on some preclinical testing work.
- 5. Also for the antiviral group, the TX-Preclinical team also just sent this link with access to more screening data, which should contain all but **b4**
 - a. "All of these compounds except b4 are part of the ReFrame library and have been tested in a SARS-CoV-2 Vero-GFP CPE assay and posted at the ReFrame database here https://reframedb.org/assays/A00440. You can create an account for free and search the data."

Please find attached the updated spreadsheet with all the new relevant compounds added for the groups to vote on. These new compounds for your groups are highlighted in green.

Finally, please find below the captured action items and key takeaways from the meeting.

Action Items

Action Items				
	Information	POC		
1	Provide Review Committee members with 5 compounds for review, along with factsheets from the R&D Consortium	Keith Gottesdiener & Elliott Levy / Stacey Adam		
2	Send updated score sheets	Stacey Adam		
3	Agent Prioritization Review Committee members (immunomodulators) score additional agents that have been added from the R&D Consortium list	AP Sub Group Members		
4	 Getting standardized, reliable data on the agents Trans-NIH information, intramural and extramural Mike Poole, Gates Foundation 	Stacey Adam / Ruxandra Draghia-Akli		
5	Ask Preclinical Working Group (R&D members) for relevant data on agents if available	Joe Menetski		
6	Get data on antivirals from NIAID and NCATS	Sarah Read/Christine Colvis		

Key Takeaways

- We are re-evaluating our list for scoring and adding other agents that were inadvertently left out
- We will not go back and re-evaluate the triage list.
- Sub Group Members voicing concern on lack of confidence in agents they've had to score. More
 research needed on drugs to understand whether these are worth putting into clinical trials. Need for
 more data.
- Suggested need to understand value of the agents we are evaluating over remdesivir.

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: b6 | Mobile: b6
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852





	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: To:	A/30/2020 11:09:57 PM Eric Hughes
CC:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner b6 Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla 66
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	b6 ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
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	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject:	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam] RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New
-	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam] RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)
Subject: Attachments:	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam] RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New
-	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam] RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added) ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-v2.xlsx; Riva2020_REFRAME drug repositioning against
Attachments: Hi All, Okay, best laid the size. So the	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam] RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added) ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-v2.xlsx; Riva2020_REFRAME drug repositioning against
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Attachments: Hi All, Okay, best laid the size. So the This will be the Thanks,	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam] RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added) ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-v2.xlsx; Riva2020_REFRAME drug repositioning against SARS-CoV-2.pdf; preprints202004.0149.v1.pdf; compound list caco cells.pdf; cell research 2020.pdf d intentions. Turns out trying to get everything in one spot meant all of your networks rejected it due to his will come to you in 2-3 emails.
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Attachments: Hi All, Okay, best laid the size. So the This will be the Thanks, Stacey	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam] RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added) ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-v2.xlsx; Riva2020_REFRAME drug repositioning against SARS-CoV-2.pdf; preprints202004.0149.v1.pdf; compound list caco cells.pdf; cell research 2020.pdf d intentions. Turns out trying to get everything in one spot meant all of your networks rejected it due to his will come to you in 2-3 emails. defirst. It has the score sheet and the antiviral info.
Attachments: Hi All, Okay, best laid the size. So the size of the size. So the size of t	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam] RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added) ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-v2.xlsx; Riva2020_REFRAME drug repositioning against SARS-CoV-2.pdf; preprints202004.0149.v1.pdf; compound list caco cells.pdf; cell research 2020.pdf d intentions. Turns out trying to get everything in one spot meant all of your networks rejected it due to his will come to you in 2-3 emails. the first. It has the score sheet and the antiviral info.
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From: Adam, Stacey (FNIH) [T]

Sent: Thursday, April 30, 2020 7:05 PM

Subject: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New

Score Sheet (Agents Added)

Importance: High

Dear TX-Clinical Agent Prioritization Subgroup,

I appreciate the candid and productive meeting that we had today. All your feedback is very helpful to refine our process for the next time.

For all of you working on scoring right now, please find attached a number of pieces of information that maybe helpful. Some if this some of your groups may have received before, however, I wanted to share it with the whole group for transparency and for having all of our reference data in one place. The information you will find attached is:

- 1. The summary spreadsheets for the agents in the host targeted category that have been added from the R&D Consortium group + 1 for Firazyr as it was requested. (one note, the group shared with us Firazyr is likely be tested in a few other trials, so that may need to be considered)
- 2. Articles on the evolving thrombosis issue that doctors are trying to deal with on the front lines. These were previously shared with the Symptomatic/Supportive therapy group.
- 3. An article relevant to immune modulator use in COVID-19.
- 4. Articles for the Antiviral group on some preclinical testing work.
- 5. Also for the antiviral group, the TX-Preclinical team also just sent this link with access to more screening data, which should contain all but EIDD-2801.
 - a. "All of these compounds except EIDD-2801 are part of the ReFrame library and have been tested in a SARS-CoV-2 Vero-GFP CPE assay and posted at the ReFrame database here https://reframedb.org/assays/A00440. You can create an account for free and search the data."

Please find attached the updated spreadsheet with all the new relevant compounds added for the groups to vote on. These new compounds for your groups are highlighted in green.

Finally, please find below the captured action items and key takeaways from the meeting.

Action Items

Action Items			
	Information	POC	
1	Provide Review Committee members with 5 compounds for review, along with factsheets from the R&D Consortium	Keith Gottesdiener & Elliott Levy / Stacey Adam	
2	Send updated score sheets	Stacey Adam	
3	Agent Prioritization Review Committee members (immunomodulators) score additional agents that have been added from the R&D Consortium list	AP Sub Group Members	
4	Getting standardized, reliable data on the agents	Stacey Adam /	

	 Trans-NIH information, intramural and extramural Mike Poole, Gates Foundation 	Ruxandra Draghia-Akli
5	Ask Preclinical Working Group (R&D members) for relevant data on agents if available	Joe Menetski
6	Get data on antivirals from NIAID and NCATS	Sarah Read/Christine Colvis

Key Takeaways

- We are re-evaluating our list for scoring and adding other agents that were inadvertently left out
- We will not go back and re-evaluate the triage list.
- Sub Group Members voicing concern on lack of confidence in agents they've had to score. More research needed on drugs to understand whether these are worth putting into clinical trials. Need for more data.
- Suggested need to understand value of the agents we are evaluating over remdesivir.

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: b6 | Mobile: b6

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852





From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	4/30/2020 11:11:55 PM
То:	Eric Hughes b6 ; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel b6 ; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike b6 ; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael b6 Keith Gottesdiener b6 ; Elliott Levy b6 Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner
CC:	b6
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	Maria [rosalvarez@deloitte.com]; Salathin, Carla b6
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	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	b6 Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject:	RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New
	Score Sheet (Agents Added)
Attachments:	lancet respiratory medicine.pdf; Amgen - Otezla (Apremilast).pdf; Takeda - Takhzyro (Lanadelumab)- summary.pdf; Takeda - Firazyr (Icatibant) -summary.pdf; Lilly-Taltz.pdf; BMS - Orencia (Apatacept).pdf; Allergan - Cenicriviroc.pdf
Hi All,	
Finally, this is	the third with the info sheets for the host targeted group.
Thanks,	
Stacey	
Stacey J. Ad	am. PhD
Director, Car	
Research Par	
Direct:	b6 Mobile: b6

From: Adam, Stacey (FNIH) [T]

Sent: Thursday, April 30, 2020 7:05 PM

Subject: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)

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	 Mike Poole, Gates Foundation 	
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Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852





From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/1/2020 2:43:13 AM Sent: To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra | b6 ; Eisner, Mark | b6]; Gottesdiener, Keith | b6 | Hughes, Eric | b6 | Judy Currier | [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa b6 } Levy, Elliot b6 }; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep **b6** Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish b6; Peppercorn, Amanda b6; Poole, Mike
b6; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588<u>067140fe988f0832c238772</u>5-Sylva.Colli]; Amanda Peppercorn b6 ; Garner, Carl b6 ; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy b6 Jansen, Kathrin b6 Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group
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 b6
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 Butcher, Tina
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 ; Demarcus
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 ; Macone, Erin
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]; Melencio, Cheryl (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla b6 ; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];

	Gonzalez, Nina [/o=Ex	changeLabs/ou=Exchange A	Administrative Group		
		cn=Recipients/cn=user3c2f4			Rose
	Li Central Account [FN	<pre>IIH@roseliassociates.com];</pre>	Anderson, Margaret [i	marganderson@deloitte.com]; Lucas	
	Smalldon	b6	; Stratton, Benjamin [bstratton@DELOITTE.com];	
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	(FYDIBOHF23SPDLT)/d	cn=Recipients/cn=35c28910)59134111a3ed28f929	042aad-RUBIND.fda]	
Subject:	Initial Follow-up to AC	CTIV Therapeutics-Clinical W	orking Group - Meetir	ng #4	
Attachments:	s: ACTIV Therapeutics-Clinical WG 30Apr2020 Meeting Guide.pdf; ACTIV_Therapeutics-Clinical_Working Group				
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Dear TX-Clinical WG Members,

Thank you for a productive discussion today and a great cross sharing of information. Please find attached the slides from today. The initial high level summary with action items and key takeaways from the meeting. The formal summary will follow tomorrow.

In addition, please know that Tim Buchman has been kind enough to provide us the slides from the thrombosis seminar held by BARDA today. However, due to their size I have had to place them on Basecamp instead of sending directly to you. You can access our WG Basecamp site at this link:

b5

If you haven't already you will need to register via the link that was sent to you two weeks ago, which if you cannot find it, please let me know and I will send again.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer Research Partnerships

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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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бене. Го:	Eric Hughes b6 ; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa];
	Ruxandra Draghia-Akli b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel b6 ; Colvis,
	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John
	b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike
	b6 ; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];
	Vincent, Michael b6 Elliott Levy
	b6 Wung, Peter /US b6 Koroshetz, Walter (NIH/NINDS) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner b6
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	Maria [rosalvarez@deloitte.com]; Salathin, Carla b6
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	b6 ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject:	RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)

Dear TX-Clinical Agent Prioritization Subgroup,

Thank you once again for a productive meeting.

I have heard from a few of you that as we discussed in the meeting you may need a little more time that until tomorrow due to the additional agents. Therefore, we are extending the deadline for scoring until 12pm ET on Sunday, May

3. We really cannot extend it further due to needing have a determination for an ACTIV Leadership Meeting early next week, so I would ask that everyone try to meet that deadline punctually.

I hope this will help with a little breathing room for scoring.

Thanks, Stacey

Stacey J. Adam, PhD Director, Cancer Research Partnerships Direct: **b6** Mobile: **b6**

From: Adam, Stacey (FNIH) [T]

Sent: Thursday, April 30, 2020 7:05 PM

Subject: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New

Score Sheet (Agents Added)

Importance: High

Dear TX-Clinical Agent Prioritization Subgroup,

I appreciate the candid and productive meeting that we had today. All your feedback is very helpful to refine our process for the next time.

For all of you working on scoring right now, please find attached a number of pieces of information that maybe helpful. Some if this some of your groups may have received before, however, I wanted to share it with the whole group for transparency and for having all of our reference data in one place. The information you will find attached is:

- 1. The summary spreadsheets for the agents in the host targeted category that have been added from the R&D Consortium group + 1 for Firazyr as it was requested. (one note, the group shared with us Firazyr is likely be tested in a few other trials, so that may need to be considered)
- 2. Articles on the evolving thrombosis issue that doctors are trying to deal with on the front lines. These were previously shared with the Symptomatic/Supportive therapy group.
- 3. An article relevant to immune modulator use in COVID-19.
- 4. Articles for the Antiviral group on some preclinical testing work.
- 5. Also for the antiviral group, the TX-Preclinical team also just sent this link with access to more screening data, which should contain all but EIDD-2801.
 - a. "All of these compounds except EIDD-2801 are part of the ReFrame library and have been tested in a SARS-CoV-2 Vero-GFP CPE assay and posted at the ReFrame database here https://reframedb.org/assays/A00440. You can create an account for free and search the data."

Please find attached the updated spreadsheet with all the new relevant compounds added for the groups to vote on. These new compounds for your groups are highlighted in green.

Finally, please find below the captured action items and key takeaways from the meeting.

Action Items

Action Items		
	Information	POC
1	Provide Review Committee members with 5 compounds for review, along with factsheets from the R&D Consortium	Keith Gottesdiener & Elliott Levy / Stacey Adam
2	Send updated score sheets	Stacey Adam
3	Agent Prioritization Review Committee members (immunomodulators) score additional agents that have been added from the R&D Consortium list	AP Sub Group Members

4	 Getting standardized, reliable data on the agents Trans-NIH information, intramural and extramural Mike Poole, Gates Foundation 	Stacey Adam / Ruxandra Draghia-Akli
5	Ask Preclinical Working Group (R&D members) for relevant data on agents if available	Joe Menetski
6	Get data on antivirals from NIAID and NCATS	Sarah Read/Christine Colvis

Key Takeaways

- We are re-evaluating our list for scoring and adding other agents that were inadvertently left out
- We will not go back and re-evaluate the triage list.
- Sub Group Members voicing concern on lack of confidence in agents they've had to score. More research needed on drugs to understand whether these are worth putting into clinical trials. Need for more data.
- Suggested need to understand value of the agents we are evaluating over remdesivir.

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer Research Partnerships

Foundation for the National Institutes of Health

Direct: **b6** Mobile: **b6**

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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla b6 Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon b6 ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject:	HOLD for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Location:	b6
Start: End: Show Time As:	5/3/2020 7:00:00 PM 5/3/2020 8:00:00 PM Tentative
Required Attendees:	Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner
Optional Attendees:	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Salathin, Carla; b6 ; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] b6
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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]				
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	b6 ; Koroshetz, Walter (NIH/NINDS) [E] b6 Higgs, Elizabeth				
cc.	(NIH/NIAID) [E] b6 ; Carlos O Garner [b6				
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] b6 ; Salathin, Carla b6 Parker, Ashley (NIH/OD) [F]				
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Location:	b6				
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	Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs,				
	Elizabeth (NIH/NIAID) [E]; Carlos O Garner				
Optional	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Salathin, Carla; b6 Parker, Ashley				
Attendees:	(NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E];				
	Ward, Jackie (NIH/OD) [E] b6				
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	b6 ; Koroshetz, Walter (NIH/NINDS) [E] b6 ; Higgs, Elizabeth		
	(NIH/NIAID) [E] b6]; Carlos O Garner b6		
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] <u>b6</u> ; Salathin, Carla		
	b6; Parker, Ashley (NIH/OD) [E]		
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] b6 ; Melencio, Cheryl (FNIH) [T] b6 ; Lucas Smalldon		
	b6 ; Walker, Paula (NIH/NINDS) [E] b6 ; Ward, Jackie		
	(NIH/NINDS) [E] b6		
Subject:	ACTIV Agent Prioritization Wave 1 Final Discussion Meeting		
Attachments:	ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-Tally.xlsx		
Location:	b6		
Start:	5/2/2020 7:00:00 DM		
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Optional Attendees:	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Salathin, Carla; b6 Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E];		
Attendees:	Ward, Jackie (NIH/OD) [E] b6		
	Wald, Jackie (Mill) OD) [L] [DB		
Hi ACTIV TX-C	linical Prioritization Subgroup members,		
Please find at	tached the final tally of scores for the agents that came through triage in Wave 1. We will use this		
	our discussions today.		
	o sent me comments, I did not want to over whelm the score sheet will multiple rows of		
	However, I have those and I will include them in the final record for posterity for this round. You can also		
	ring them up during the discussion if helpful to the group.		
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Thanks,			
Stacey			
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Attaching the most recent version of the innovations matrix. Karen

Dear Colleagues, Agenda is attached. During this call we will hear the latest from the three sub-WGs – innovations, inventory, and survey – which have been working very hard to move their activities forward quickly. Many thanks to all! We will also have a bit of a brainstorming session about creating a 'dashboard' to use in analyzing survey results. Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards, Karen

Karen H. Tountas, PhD Scientific Program Manager Foundation for the National Institutes of Health

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD] 5/1/2020 1:33:02 PM Sent: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry ; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael **b6** ; Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Hudson, Thomas ; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John b6 ; Meeker, David b6 ; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Pangalos, Meno b6; Pao, Williamb6; Paul, Steveb6;Perlmutter, Rogerb6; Plump, Andyb6; Rasi, Guidob6; Reed, Johnb6; Rouse, Dorisb6; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul **b6**; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, FYDIBOHF23SPDLT, Young, FYDb6 ; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy b6 ; Hughes, Eric b6 ; Jansen, Kathrin ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Gonzalez, Nina [ningonzalez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Stratton, Ben [bstratton@deloitte.com]; Tolman,

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Dr. Burklow just forwarded the invite to Renate Myles

----Original Appointment----

From: Melencio, Cheryl (FNIH) [T] On Behalf Of Wholley, David (FNIH) [T]

Sent: Friday, April 24, 2020 11:37 AM

To: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Freire, Maria (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Rachel Ramoni; Plenge, Robert; Talley, Michael; Cavaleri, Marco; Lee, William; Anderson, James (NIH/OD) [E]; Bianchi, Diana (NIH/NICHD) [E]; Brennan, Patti (NIH/NLM) [E]; Byrnes, Noni (NIH/CSR) [E]; Carter, Robert (NIH/NIAMS) [E]; Glass, Roger (NIH/FIC) [E]; Hodes, Richard (NIH/NIA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Norris, Andrea (NIH/CIT) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; Schwetz, Tara (NIH/OD) [E]; Sharpless, Norman (NIH/NCI) [E]; Tucci, Debara (NIH/NIDCD) [E]; Tumminia, Santa (NIH/NIE) [E]; Volkow, Nora (NIH/NIDA) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lankford, David (NIH/OD)

[E]; Gibbons, Gary (NIH/NHLBI) [E]; Koob, George (NIH/NIAAA) [E]; Hallett, Adrienne (NIH/OD) [E]; Valantine, Hannah (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]; Woychik, Rick (NIH/NIEHS) [E]; Cihlar, Tomas; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Langevin, Helene (NIH/NCCIH) [E]; Lauer, Michael (NIH/OD) [E]; Gallin, John (OD) [E] Cc: Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Simon, Dina (NIH/OD) [C]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; FNIH Central Account; Sepulveda, Dorina (FNIH) [T]; Li, Rose; Zottoli, Jessica; Lowy, Douglas (NIH/NCI) [E]; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Elsaid, Olivia; Best, Cindy (NIH/NEI) [E]; Bronson, Charlette (NIH/NIA) [E]; Dzokoto-Pomenya, Caroline (NIH/OD) [C]; Hamid, Khawar (NIH/CSR) [E]; Hardesty, Rebecca (NIH/OD) [C]; Hughes, Karen (NIH/OD) [E]; Kellton, Karen (NIH/OD) [C]; Mowery, Penny (NIH/NIDDK) [E]; New, Suzanne (NIH/NIDCR) [E]; Ott, Sandra (NIH/NICHD) [E]; Salley, Jasmine (NIH/NIDDK) [C]; Schulke, Hilda (NIH/NIDA) [E]; Shapiro-Loser, Beth (NIH/NIDDK) [E]; Stover, Kathleen (NIH/FIC) [E]; Togashi, Mieko (NIH/NCI) [E]; Wade, Portia (NIH/CIT) [E]; Barnett, Sylvia (NIH/OD) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Castillejos zenteno, Carlos [JRDUS]; Oresanya, Jejelola (NIH/OD) [C]; McBurney, Margaret (NIH/OD) [E]; Smith, Spencer (NIH/NIEHS) [E]; Denny, Joshua (NIH/OD) [E]; Council, Lisa (NIH/NCCIH) [C]; Meltzer, Abbey (FNIH) [T]; Gorman, Greta (FNIH) [T]; Myles, Renate (NIH/OD) [E]

Subject: ACTIV Response Partnership Leadership Team Meeting #3 When: Wednesday, May 6, 2020 3:30 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada). b6 Where: Join Zoom Meeting Meeting ID: b6 Password: One tap mobile US (Germantown) **b6** US (Chicago) Dial by your location US (Germantown) US (Chicago) US (New York) US (Houston) US (San Jose) US (San Jose) US (Tacoma) Meeting ID: b6 Password: **b6** Find your local number: b6

Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD] 5/1/2020 1:33:24 PM Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry j; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael ; Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Hudson, Thomas ; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) Meeker, David **b6**; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Pangalos, Mene b6Pao, Williamb6Paul, Steveb6Perlmutter, Rogerb6Plump, Andyb6Rasi, Guidob6Reed, Johnb6Rouse, Dorisb6Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul ; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Vessey, Rupert Virgin, Skip b6; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; ; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Young, John **b6** Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis];

Desrosiers, Betsy b6 ; Hughes, Eric b6 ; Jansen, Kath **b6**; Hughes, Eric **b6**; Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Gonzalez, Nina [ningonzalez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group

From:

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000000000000000000000000000000000000000	(FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Plenge, Robert
	b6]; b6]; Cavaleri, Marco
	b6 Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5];
	Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Gadbois, Ellen (NIH/OD)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Tsai, John
	b6
CC:	Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Burrus-Shaw, Cyndi
	(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Conrad, Patricia
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Hoffstetter, Renata
	(FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide
	b6 ; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; McManus, Ayanna
	(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Protasiewicz, Ann
	b6 ; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Thomas, Ashley
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; FNIH Central Account
	[FNIH@roseliassociates.com]; Li, Rose b6 ; Zottoli, Jessica b6
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140 faa 95aaaa fe 06ebd 70-parker as]; Gladman, Jordan (NIH/OD) for the contraction of the contrac
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]; Elsaid, Olivia
	[oelsaid@deloitte.com]; Castillejos zenteno, Carlos [JRDUS] b6 Dimishkov, Roxanne (NIH/NHLBI)
	[C] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Burklow, John
	(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Wolinetz, Carrie (NIH/OD)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Myles, Renate (NIH/OD)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Hallett, Adrienne (NIH/OD)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Chen, Helen
	[qingchen@deloitte.com]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Meltzer, Abbey (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Gorman, Greta (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Dana Carluccio

Attachments: Materials for June 3 ACTIV Partnership Leadership Call Location: Start: 6/3/2020 4:00:00 PM End: 6/3/2020 5:30:00 PM Show Time As: Busy Required Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Attendees: Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Freire, Maria (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Rachel Ramoni; Plenge, Robert; Talley, Michael; b6 ; Cavaleri, Marco; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Gibbons, Gary (NIH/NHLBI) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E] Optional Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia Attendees: (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Simon, Dina (NIH/OD) [C]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]; FNIH Central Account; Li, Rose; Zottoli, Jessica; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Elsaid, Olivia; Castillejos zenteno, Carlos [JRDUS]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Burklow, John (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Chen, Helen; Lowy, Douglas (NIH/NCI) [E]; Meltzer, Abbey (FNIH) [T]; Gorman, Greta (FNIH) [T]; Dana Carluccio Join Zoom Meeting b6 Meeting ID: Password: **b6** One tap mobile US (Chicago) **b6** US (New York) Dial by your location US (Chicago) US (New York) US (Germantown) US (Tacoma) US (Houston) US (San Jose) US (San Jose) b6 Meeting ID: Password: Find your local number:

ACTIV Response Partnership Leadership Team Meeting #4

Subject:

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/1/2020 1:36:56 PM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner ; Keith Gottesdiener **b6**; Eric Hughes b6LaVange, Lisa Mb6; Elliott Levyb6b6; Amanda Peppercornb6 Proschan, Michael Menon (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael ; Wung, Peter /US b6; Macone, Erin b6; Macone, Erin b6; CC: Mary Biggs b6 Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc) Subject: Material for ACTIV TX-Clinical Master Protocol Subgroup Meeting #11 Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_1May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting Agenda_05012020.pdf Dear TX-Clinical Master Protocol Subgroup, Please find attached the materials for today's meeting. Please let me know if you have any questions. Thanks, Stacey Stacey J. Adam, PhD

Director, Cancer

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/1/2020 1:36:58 PM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner b6 ; Keith Gottesdiener ; Eric Hughes Sandeep ; Amanda Peppercorn Proschan, Michael b6 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn ; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael b6 , Macone, Erin b6 Wung, Peter /US]; Demarcus CC: Mary Biggs Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina b6 Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc) Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #11 ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting Agenda_05012020.pdf; ACTIV Therapeutics-Attachments: Clinical_MP Subgroup_1May2020 Meeting Guide.pdf Location: Start: 5/1/2020 3:00:00 PM 5/1/2020 4:00:00 PM Show Time As: Tentative

Required Attendees:

Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne

(FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US Optional Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T] Dear TX-Clinical Master Protocol Subgroup, Please find attached the materials for today's meeting. Please let me know if you have any questions. Thanks, Stacey Join Zoom Meeting **b6** Meeting ID: Password: b6 One tap mobile US (Chicago) **b6** US (New York) Dial by your location US (Chicago) US (New York) US (San Jose) US (San Jose) US US US (Houston) Meeting ID: b6 Password: b6

b6

Find your local number:

From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	5/1/2020 3:05:03 PM
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	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa];
	Ruxandra Draghia-Akli b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel b6 ; Colvis,
	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John
	b6 []; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike
	b6 ; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];
	Vincent, Michael b6 ; Keith Gottesdiener b6 ; Elliott Levy
	b6 ; Wung, Peter /US b6 Koroshetz, Walter (NIH/NINDS) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner
	b6
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	Maria [rosalvarez@deloitte.com]; Salathin, Carla b6
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject:	Agenda for ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #6
Attachments:	ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting Agenda_05012020v2.pdf
Attacimients.	ACTIV Therapeutics chilical_Agent Frioritization Sub-Group Meeting Agenda_05012020V2.pdf
Dear TX-Clinic	cal Agent Prioritization Subgroup,
Please find at	tached the agenda for today's call. We will be continuing the discussions from yesterday.
Thanks,	
Stacey	
Stacey	
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Stacey J. Ad	
Director, Car	
Research Par	tnerships
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	US (Germantown)	
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NU	US (San Jose)	
	US (Tacoma)	
	US (Houston)	
Meeting ID: b6		
Password: b6		
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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	5/1/2020 3:05:14 PM
Sent: To:	Eric Hughes
CC:	b6 Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	Maria [rosalvarez@deloitte.com]; Salathin, Carla b6
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Carlatana	ACTIVITY Clinical Accord Delivities time Culture Managing MC
Subject: Attachments:	ACTIV Therapouties Clinical Agent Prioritization Subgroup Meeting #6
Location:	ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting Agenda_05012020v2.pdf b6
Location.	
Start:	5/1/2020 7:00:00 PM
End:	5/1/2020 8:30:00 PM
Show Time As:	
Required	Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine
Attendees:	(NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR);
	Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs,
	Elizabeth (NIH/NIAID) [E]; Carlos O Garner
Optional	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; b6 Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula
Attendees:	Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula
	(NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] b6
Dear TX-Clinic	al Agent Prioritization Subgroup,
Please find att	tached the agenda for today's call. We will be continuing the discussions from yesterday.
Thanks.	

Stacey

Join Zoom Meeting b6 Meeting ID: b6 Password: b6 One tap mobile US (Chicago) **b6** US (New York) Dial by your location US (Chicago) US (New York) US (Germantown) US (San Jose) US (San Jose) US (Tacoma) US (Houston) Meeting ID: b6 Password: **b6** b6 Find your local number:

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]

Sent: 5/1/2020 4:06:29 PM

To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Melencio, Cheryl (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Santos, Michael (FNIH)

[T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]

Subject: DoD invitation: note to invite Colonel Nelson Michael to the ACTIV Vaccines WG Attachments: ACTIV Partnership Leadership Meeting QA Follow Up_20200424 final.docx

Francis

First of three for you to edit and send. Copying Ashley on all in case she wants to have a look/advise on these.

Here is note for Colonel Nelson Michael Director, Center for Infectious Diseases Research Walter Reed Army Institute of Research

	;
Email:	b6
	U

Dear Colonel Michael,

I am writing to you at the suggestion of Brigadier General Michael Talley. As you know well, addressing the COVID-19 pandemic is an urgent priority for the entire biomedical research community. While the response has been broad and immediate, with many individuals and organizations already dedicated to applying their capabilities to respond, the field needs to find a way to focus and prioritize these many efforts, as there is of course a critical need for effective treatments and vaccines.

NIH has been working at the forefront of addressing the crisis, including rapidly launching its own clinical trials of therapeutics and of course working with other government agencies and individual companies on accelerated testing of vaccines and therapeutics. In order to broaden the response on April 17 we announced ACTIV, a new public-private partnership with FDA, BARDA, industry, and academic scientists to further accelerate progress against COVID and the threat of future pandemics. We have since added representatives from the Veterans Administration and, in recognition of the valuable work and capabilities of the DoD in these and other fields of medical research, approached BG Talley earlier this week to see if there would be interest in adding representatives from the Department to our partnership.

As described in the attached meeting notes (from our kick-off on April 3) we have now set up Working Groups to decide efforts in four key areas—accelerating preclinical therapeutic development, optimizing clinical therapeutic development, coordinating clinical trials capacity, and supporting effective vaccine development. At the suggestion of BG Talley, I would like to invite you to join as **a member on the Vaccines Working Group** which is being co-chaired by Doug Lowy, NCI and Kathrin Jansen, Pfizer. While this group has been meeting for several weeks, there are many decisions still be made and many areas of discussion that can benefit from your insights and expertise.

Please direct your response to this invitation to Mike Santo	b6	of the Foundation for the NIH, who will
fill you in on the mission and progress of the Working Group and	get you i	ntegrated into meeting logistics. I look forward
to your contributions to this critical effort.		

Best,

Francis Collins

Sent: 5/1/2020 5:48:38 PM **To**: **b6**

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]

Subject: ACTIV partnership on COVID-19

Attachments: FNIH Covid 19 meeting April 03 2020 notes.docx

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Best, Francis Collins From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]

Sent: 5/1/2020 5:56:21 PM

To: b6

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Santos, Michael (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]

Subject: ACTIV partnership on COVID-19

Attachments: FNIH Covid 19 meeting April 03 2020 notes.docx

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to your contributions to this critical effort.		

Best, Francis Collins From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]

Sent: 5/1/2020 6:13:17 PM

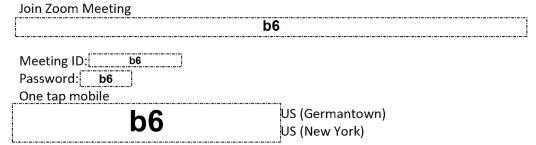
Subject: *ACTIV Vaccine Discussion **Location**: Zoom link in the calendar entry

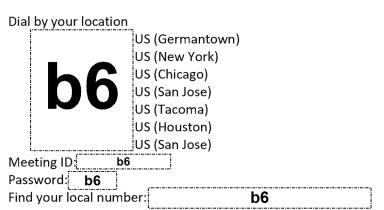
Start: 5/2/2020 8:00:00 PM **End**: 5/2/2020 9:00:00 PM

Show Time As: Busy

Recurrence: (none)

Meeting to discuss ACTIV vaccines program





Hi Patty,

Thanks so much. I believe we now have agreement from everyone on 4pm tomorrow, with the completely understandable caveat about Tony's schedule. I will send an invite soon.

Thanks, Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Conrad, Patricia (NIH/NIAID) [E] b6
Sent: Friday, May 1, 2020 1:31 PM
To: Santos, Michael (FNIH) [T] b6 ; Barasch, Kimberly (NIH/NIAID) [C]
66 (A)
Cc: Tolman, Brett b6
1
Awwad, David (NIH/NIAID) [C] <u>b6</u> Subject: RE: Call with Vaccines WG co-chairs
Subject. N.E. can with vaccines we co-chairs
Hi Mike-
4 pm tomorrow should be fine. Please know that Dr. Fauci's calendar is always subject to change given he is often called to the White House. Will do our best to keep this on.
Please include both Kim and David – both cc'd here – with any calendar makers/adjustments.
Many thanks,
-patty
From: Santos, Michael (FNIH) [T] b6 Sent: Friday, May 1, 2020 12:35 PM To: Conrad, Patricia (NIH/NIAID) [E] b6 ; Barasch, Kimberly (NIH/NIAID) [C]
b6 / / / / / / / / / / / / / / / / / / /
Cc: Tolman, Brett_ btolman@deloitte.com>; Wood, Gretchen (NIH/OD) [E] b6 Melencio,
Cheryl (FNIH) [T] b6
Subject: RE: Call with Vaccines WG co-chairs
Thanks, Gretchen!
Hi Patty and Kim,
Francis is trying to set up a meeting this weekend with Tony, Cliff Lane, John Mascola, Peter Marks, Kathrin Jansen, Doug Lowy, David Wholley, and me. The note below says that tomorrow is better for Tony than Sunday. Based on what I know so far, tomorrow 4pm or later seems to be the overlap in availability (pending hearing from John and Peter Marks). Would 4pm or later work for Tony?
Thanks,
Mike
Michael Santos, PhD Associate Vice President, Science Foundation for the National Institutes of Health
From: Wood, Gretchen (NIH/OD) [E] b6
Sent: Friday, May 1, 2020 12:30 PM
To: Santos, Michael (FNIH) [T] 66

Cc: Tolman, Brett < btolman@deloitte.com >; Melencio, Cheryl (FNIH) [T] b6 ; Conrad,
Cc: Tolman, Brett < btolman@deloitte.com >; Melencio, Cheryl (FNIH) [T] < b6 }; Conrad, Patricia (NIH/NIAID) [E] b6 ; Barasch, Kimberly (NIH/NIAID) [C]
b6
Subject: Re: Call with Vaccines WG co-chairs
Hi Mike,
Sure, I have cc'd Patty and Kim from Dr. Fauci's office. They can help.
Dest with an
Best wishes,
Cratchan
Gretchen
From: "Santos Michael (ENILL) [T]"! h6
From: "Santos, Michael (FNIH) [T]" b6 Date: Friday, May 1, 2020 at 12:25 PM
To: Gretchen Wood Cc: "Tolman, Brett" Melencio, Cheryl (FNIH) [T]" Subject: FW: Call with Vaccines WG co-chairs
Subject: FW: Call with Vassines WG so shairs
Subject: FW: Call with vaccines WG co-chairs
Hi Crataban
Hi Gretchen,
It looks like wa're caboduling a mosting tomorrow with Francis Toni Fausi Cliff Lang John Massela Data
It looks like we're scheduling a meeting tomorrow with Francis, Toni Fauci, Cliff Lane, John Mascola, Pete
Marks, Kathrin Jansen, Doug Lowy, David Wholley, and me.
Do you have advice on how best to schedule with Toni Fausi , whom should I contact? I think I have the
Do you have advice on how best to schedule with Toni Fauci – whom should I contact? I think I have the information to schedule with the rest of them.
mormation to schedule with the rest of them.
Thanks,
Mike
Wirke
Michael Santos, PhD
Associate Vice President, Science Foundation for the National Institutes of Health
From: Wholley, David (FNIH) [T] { b6
Sent: Friday, May 1, 2020 9:22 AM
To: Santos, Michael (FNIH) [T] b6
Subject: FW: Call with Vaccines WG co-chairs
·
From: Lane, Cliff (NIH/NIAID) [E] b6
Sent: Friday, May 1, 2020 9:19 AM
To: Collins, Francis (NIH/OD) [E] b6; Wholley, David (FNIH) [T] b6; Freire, Maria (FNIH) [T] b6; Tabak, Lawrence (NIH/OD) [E] b6;
Freire, Maria (FNIH) [T] b6 ; Tabak, Lawrence (NIH/OD) [E] b6 ;
Parker, Ashley (NIH/OD) [E] b6
Parker, Ashley (NIH/OD) [E] b6 Cc: Wood, Gretchen (NIH/OD) [E] b6 McManus, Ayanna (NIH/OD) [E]
b6
Subject: Re: Call with Vaccines WG co-chairs

2-4 is bad for me.

Cliff

From: "Collins, Francis (NIH/OD) [E]" b6			
Date: Friday, May 1, 2020 at 9:15	AM			
To: "Wholley, David (FNIH) [T]"	b6	"Freire, Maria (FNIH) [T]" {b6	, Lawrence
Tabak b6	, "Austin, Christor	oher (NIH/NCATS) [E]"[b6	, "Lane, Cliff
(NIH/NIAID) [E]" b6	, "Parker, As	shley (NIH/OD) [E]'	b6	, "Anderson,
James (NIH/OD) [E]"[b6			
Cc: "Wood, Gretchen (NIH/OD) [E] b6	, "McManus, Ayaı	nna (NIH/OD) [l	Ε]"
b6				
Subject: Call with Vaccines WG co	-chairs			

Hi David,

Tony says yes to joining. Agrees we should also have Peter Marks. Also wants John Mascola and Cliff Lane.

Saturday is better for Tony. I can make myself available anytime except 8:30 – 9:15. Can you work on that?

FC

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR] Sent: 5/1/2020 6:14:54 PM To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jansen, Kathrin ; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd] CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Awwad, David (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a5171ce4c4d4110abfe9aebfbdafbe7-dawwad]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Zottoli, Jessica **b6** ; Johnson, Maureen (NIH/NCI) [E] ; Hopps, Markay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc] Subject: **ACTIV** vaccines discussion Attachments: Vaccine call with NIH, NIAID, FDA, ACTIV Co-Chairs 050220.docx Location: 5/2/2020 8:00:00 PM Start: 5/2/2020 9:00:00 PM Show Time As: Busy Required Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) Attendees: [E]; Mascola, John (NIH/VRC) [E]; Marks, Peter (FDA/CBER); Parker, Ashley (NIH/OD) [E]; Jansen, Kathrin; Lowy,

Douglas (NIH/NCI) [E]; Wholley, David (FNIH) [T]

Optional Attendees:

Wood, Gretchen (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Conrad, Patricia (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Awwad, David (NIH/NIAID) [C]; Austin, Sarah (NIH/NIAID) [E]; Zottoli, Jessica; Hopps, Markay; Johnson, Maureen (NIH/NCI) [E]; Kozlowski, Mary (NIH/NCI) [C]; Melencio, Cheryl (FNIH) [T]

Meeting to discuss ACTIV vaccines program

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From:	Santos, Michael (FNIH) [T] [/C (FYDIBOHF23SPDLT)/CN=REC						
Sent:	5/1/2020 6:14:54 PM	TIENTS/ CN-ABSOC	.000300244210	521 40005521 051 0	o santosining		
To:		=ExchangeLabs/ou	=Exchange Adr	ministrative Group)		
	Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Collins, Francis (NIH/OD)						
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recip	-	•	3e50d2ff0b6c2-co	llinsfl: Tabak, La	wrence (NIH/OD)	
		; Fauci, Anthony (N				(NIH/NIAID) [E]	
		la, John (NIH/VRC)			arks, Peter (FDA)		
		Parker, Ashley (NIH,	/OD) [E]	b6	; Jansen, Kathri	•	
		Lowy, Douglas (NI		b6	Wholley, David		
	b6		,		1	. ,	
CC:	Wood, Gretchen (NIH/OD) [E]	b6	; Simon, Di	na (NIH/OD) [C]	b6	; Conrad,	
	Patricia (NIH/NIAID) [E]	b6		nberly (NIH/NIAID) [C]	b6 ;	
	Awwad, David (NIH/NIAID) [C] b6	Austin	, Sarah (NIH/NIAI	D) [E]	b6	
	Zottoli, Jessica bo	; Hop	ps, Markay	b6		on, Maureen	
	(NIH/NCI) [E] L b6		wski, Mary (NII	H/NCI) [C] [b6	; Melencio,	
	Cheryl (FNIH) [T] b6		, , ,	′ · · L		J	
	, , , , , , , , , , , , , , , , , , ,	<u></u>					
Subject:	ACTIV vaccines discussion						
Location:	Zoom:		b6				
	\						
Start:	5/2/2020 8:00:00 PM						
End:	5/2/2020 9:00:00 PM						
Show Time As:	Tentative						
Required	Collins, Francis (NIH/OD) [E];	Гаbak, Lawrence (N	IIH/OD) [E]; Fau	uci, Anthony (NIH,	/NIAID) [E]; Lane	e, Cliff (NIH/NIAID)	
Attendees:	[E]; Mascola, John (NIH/VRC)	[E]; Marks, Peter (F	DA/CBER); Par	ker, Ashley (NIH/0	OD) [E]; Jansen,	Kathrin; Lowy,	
	Douglas (NIH/NCI) [E]; Wholle	y, David (FNIH) [T]					
Optional	Wood, Gretchen (NIH/OD) [E]	; Simon, Dina (NIH,	/OD) [C]; Conra	id, Patricia (NIH/N	IIAID) [E]; Baraso	ch, Kimberly	
Attendees:	(NIH/NIAID) [C]; Awwad, Davi						
	Johnson, Maureen (NIH/NCI)						
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Meeting to dis	scuss ACTIV vaccines progra	m					
Join Zoom Me	eting						
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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS] Sent: 5/1/2020 8:17:17 PM To: Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm] Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion OK, I will let the FNIH scheduler know. Thanks From: Simon, Dina (NIH/OD) [C] Sent: Friday, May 1, 2020 4:12 PM b6 To: Parker, Ashley (NIH/OD) [E] Subject: Re: Meeting Forward Notification: ACTIV vaccines discussion Yes, LAT will be attending. Thanks for checking. D Get Outlook for iOS From: Parker, Ashley (NIH/OD) [E] b6 Sent: Friday, May 1, 2020 3:47:59 PM To: Simon, Dina (NIH/OD) [C] b6 Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion OK, thanks - he was not included on the invite FNIH sent but I think it may have been an oversight. From: Simon, Dina (NIH/OD) [C] b6 Sent: Friday, May 1, 2020 3:46 PM To: Parker, Ashley (NIH/OD) [E] b6 Subject: Re: Meeting Forward Notification: ACTIV vaccines discussion Hi Ashely, Let me confirm his attendance and I will get back with you shortly. Thanks, Dina Get Outlook for iOS From: Parker, Ashley (NIH/OD) [E] Sent: Friday, May 1, 2020 3:07:21 PM b6 To: Simon, Dina (NIH/OD) [C] Subject: Re: Meeting Forward Notification: ACTIV vaccines discussion Hi Dina, I did not see Larry included on the invite for tomorrow's vaccine meeting that FNIH sent out. Am I correct that he should

be included?

APAR0000014042

Tee d you on the mitte that Frorwarded for 4pm tomorrow.
Thanks, Ashley
From: Santos, Michael (FNIH) [T] b6 Sent: Friday, May 1, 2020 3:00 PM To: Parker, Ashley (NIH/OD) [E] b6 Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion
Hi Ashley,
My understanding of the participants (which could certainly be incomplete), in addition to you, was: Francis Tony Cliff John Mascola Peter Marks Kathrin Jansen Doug Lowy David Wholley Me So that's where the invite went (plus assistants). Of course happy to have anyone else that Francis/you would like. Looking forward to the conversation.
Thanks, Mike
Michael Santos, PhD Associate Vice President, Science Foundation for the National Institutes of Health
From: Parker, Ashley (NIH/OD) [E] b6 Sent: Friday, May 1, 2020 2:23 PM To: Santos, Michael (FNIH) [T] b6 Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion I was trying to ask but seems this went to the entire group? No apologies needed.
From: Santos, Michael (FNIH) [T] b6 Sent: Friday, May 1, 2020 2:22 PM To: Parker, Ashley (NIH/OD) [E] b6 Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion
Hi Ashley,
Does Larry plan to join as well? Apologies that he wasn't on the initial list.
Thanks, Mike
Michael Cantos Dhib

Associate Vice President, Science | Foundation for the National Institutes of Health

----Original Appointment----

From: Microsoft Outlook < MicrosoftExchange 329e71ec88ae4615bbc36ab6ce41109e@nih.mail.onmicrosoft.com > On

Behalf Of Parker, Ashley (NIH/OD) [E] **Sent:** Friday, May 1, 2020 2:20 PM **To:** Santos, Michael (FNIH) [T]

Subject: Meeting Forward Notification: ACTIV vaccines discussion

When: Saturday, May 2, 2020 8:00 PM-9:00 PM (UTC+00:00) Monrovia, Reykjavik.

Where: Zoom: b

Your meeting was forwarded

Parker, Ashley (NIH/OD) [E] has forwarded your meeting request to additional recipients.

Meeting

ACTIV vaccines discussion

Meeting Time

Saturday, May 2, 2020 4:00 PM-5:00 PM.

Recipients

Tabak, Lawrence (NIH/OD) [E]

Simon, Dina (NIH/OD) [C]

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

Sent by Microsoft Exchange Server

Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR] Sent: 5/1/2020 8:34:09 PM To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras] CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd] Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion Great, thanks. I have added him to the invite. Michael Santos, PhD Associate Vice President, Science | Foundation for the National Institutes of Health From: Parker, Ashley (NIH/OD) [E] b6 Sent: Friday, May 1, 2020 4:18 PM To: Santos, Michael (FNIH) [T] b6 Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion Thank you – yes, Dr. Tabak should be included. From: Santos, Michael (FNIH) [T] b6 **Sent:** Friday, May 1, 2020 3:06 PM To: Parker, Ashley (NIH/OD) [E] b6 Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion Hi Ashley, I do not believe anyone else (including me) can see your message. I received a notice saying that you had forwarded the invite to Dr. Tabak, but not any text along with it. The invite on my calendar doesn't contain any content other than what I sent. So I think we're all set. Thanks, Mike Michael Santos, PhD Associate Vice President, Science | Foundation for the National Institutes of Health From: Parker, Ashley (NIH/OD) [E] b6 Sent: Friday, May 1, 2020 3:03 PM To: Santos, Michael (FNIH) [T] Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion

Hi Mike,

I will follow up with Dr. Tabak to see if needs to join and circle back with you. Can you go in the invite and remove my message – this was not intended for anyone except for you, Dr. Tabak, and his assistant.

Thank you, Ashley

From: Santos, Michael (FNIH) [T] b6 Sent: Friday, May 1, 2020 3:00 PM To: Parker, Ashley (NIH/OD) [E] b6 Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion
Hi Ashley,
My understanding of the participants (which could certainly be incomplete), in addition to you, was: Francis Tony Cliff John Mascola Peter Marks Kathrin Jansen Doug Lowy David Wholley Me
So that's where the invite went (plus assistants). Of course happy to have anyone else that Francis/you would like. Looking forward to the conversation.
Thanks, Mike
Michael Santos, PhD Associate Vice President, Science Foundation for the National Institutes of Health
From: Parker, Ashley (NIH/OD) [E]
From: Santos, Michael (FNIH) [T] b6 Sent: Friday, May 1, 2020 2:22 PM To: Parker, Ashley (NIH/OD) [E] b6 Subject: RE: Meeting Forward Notification: ACTIV vaccines discussion
Hi Ashley,
Does Larry plan to join as well? Apologies that he wasn't on the initial list.
Thanks, Mike
Michael Santos, PhD Associate Vice President, Science Foundation for the National Institutes of Health
Original Appointment From: Microsoft Outlook < MicrosoftExchange329e71ec88ae4615bbc36ab6ce41109e@nih.mail.onmicrosoft.com > On Behalf Of Parker, Ashley (NIH/OD) [E]

Sent: Friday, May 1, 2020 2:20 PM **To:** Santos, Michael (FNIH) [T]

Subject: Meeting Forward Notification: ACTIV vaccines discussion

When: Saturday, May 2, 2020 8:00 PM-9:00 PM (UTC+00:00) Monrovia, Reykjavik.

Where: Zoom: b6

Your meeting was forwarded

Parker, Ashley (NIH/OD) [E] has forwarded your meeting request to additional recipients.

Meeting

ACTIV vaccines discussion

Meeting Time

Saturday, May 2, 2020 4:00 PM-5:00 PM.

Recipients

Tabak, Lawrence (NIH/OD) [E]

Simon, Dina (NIH/OD) [C]

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

Sent by Microsoft Exchange Server

From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	5/1/2020 9:25:06 PM
Го:	Eric Hughes b6; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa];
	Ruxandra Draghia-Akli b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel b6 ; Colvis,
	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John
	b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike
	Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];
	Vincent, Michael b6 ; Keith Gottesdiener b6 ; Elliott Levy
	b6 Wung, Peter /US b6 Koroshetz, Walter (NIH/NINDS) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner
	b6
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
cc.	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	b6 Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Stratton, Benjamin
	[bstratton@DELOITTE.com]
Subject:	Follow-up from ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #6
Attachments:	ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-v3.xlsx; 2020-04-30-
	_TX_Clinical_WG_Agent_Prioritization_Sub-WG_Summary.pdf; ACTIV_Therapeutics-Clinical_AP Sub-Group Meeting
	6_Key Takeaways_05012020v2.docx

Dear TX-Clinical Agent Prioritization Subgroup,

Thank you all for a great call! Mike, thanks especially for sharing what Gates is doing.

As discussed on the call, please find attached the new Wave 1 Score Sheet with the additional scoring category for insufficient data.

Also, please find attached the formal summary of the call yesterday and the high level notes and action items from today's call. Please let me know if you have any additions or amendments.

Happy scoring and see you all on Sunday!

Thanks, Stacey Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

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From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]

Sent: 5/1/2020 11:33:48 PM

To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

Subject: Fwd: Update on other COVID "master protocol" efforts

Flag: Follow up

Francis Did you bring this up with Gary?

Sent from my iPhone

Begin forwarded message:

From: "Wholley, David (FNIH) [T]"	b6				
Date: May 1, 2020 at 7:12:15 PM EDT					
To: "Collins, Francis (NIH/OD) [E]"	b6				
Cc: "Tabak, Lawrence (NIH/OD) [E]"	b6				
Subject: Update on other COVID "master protocol" efforts					

Hi Francis,

I sat in on several of the Working Group calls today and had my daily update with my team and one with Deloitte. I learned:

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Regards, David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/2/2020 1:44:28 AM Sent: To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra b6 } Eisner, Mark b6 ; Gottesdiener, Keith b6 Hughes, Erid b6 ; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa b6 ; Levy, Elliot b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep b6 ; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish | b6 | ; Peppercorn, Amanda | b6 | ; Poole, Mike | b6 | ; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy

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Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Stratton, Benjamin [bstratton@DELOITTE.com]; Qashu,

Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-gashufm]; Rubin, Daniel B.

(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject: Follow-up Materials from ACTIV Therapeutics-Clinical Working Group - Meeting #4

Attachments: ACTIV Therapeutics-Clinical WG 30Apr2020 Meeting Guide.pdf; 2020-04-30_TX-Clinical_WG_Meeting_Summary-

v2.pdf; ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-v3.xlsx

Dear TX-Clinical WG Members,

I know that I say it a lot, but truly, thank you for all that you have done this week. Despite the need to improve processes and the tight timelines, you all have done so much work over the last three weeks! THANK YOU!

In follow-up to yesterday's meeting, please find attached the following materials:

- The formal meeting summary
- 2. The slides that were presented (Some members wished to have them again)
- The Agent Prioritization Scoring Sheet that has both the Triage Record and the Final Compounds that are being scored by the Agent Prioritization Committee. Please keep in mind that the ~170 agents that under went triage, we already whittled down from a list of ~400 compounds that we pulled from public data bases. We will continuously update our list from new sources and refine the information for each wave of prioritization. We will begin with the 400+ each time unless an agent is decided to be unsafe or unsuitable for COVID-19.

As always, please let me know if you have any questions or amendments to the record.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]

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To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf] Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]

Subject: RE: Update on other COVID "master protocol" efforts

Yes: although Walter has been participating directly in some of our WG calls of late I do think a conversation with him would be important.

From: Collins, Francis (NIH/OD) [E] 6

Sent: Saturday, May 2, 2020 10:29 AM

To: Wholley, David (FNIH) [T] 66

Cc: Tabak, Lawrence (NIH/OD) [E] 66

Subject: RE: Update on other COVID "master protocol" efforts

This is indeed a cause for serious concern. See my note about a conversation I had with Gary Gibbons yesterday, and the need to bring NHLBI back into the tent.

Do I need to have the same conversation with Walter Koroshetz?

FC

CC:

From: Wholley, David (FNIH) [T] b6

Sent: Friday, May 1, 2020 7:12 PM

To: Collins, Francis (NIH/OD) [E] b6

Cc: Tabak, Lawrence (NIH/OD) [E] b6

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CC:	Mary Biggs	b6	Demarcus	b6	;	Macone, Erin	b6	;	
	Tountas, Karen (FNIF	l) [Т] [/o=Ехс	hangeLabs/ou=Ex	change Administr	ative Gr	oup			
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	[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]								
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	Document - 28 April	Document - 28 April 2020 DRAFT[1].pdf; REMAP-CAP design and rationale (in press) (1).pdf; REMAP-COVID core							
	protocol V.2.0.pdf; m	ns_4-30.pdf							

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the follow-up materials from yesterday's meeting.

- 1. The summary of key takeaways and action items from the discussion. Please let us know if we have missed any thing critical.
- 2. The documents for REMAP-COVID for review for our conversation with that team next Friday.
 - a. REMAP-COVID core protocol
 - b. REMAP-CAP rationale
 - c. REMAP-COVID simulations

3. Meta-analysis manuscript for the combination of data from remdesivir trials that Lisa discussed from the PI at UNC. This was discussed in the context of potentially considering a partially synthetic control arm for our trial if we are having challenges with getting remdesivir for SoC.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

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	b6
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
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	Maria [rosalvarez@deloitte.com]; Salathin, Carla b6
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject:	Follow-up to ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #6
Attachments:	2020-05-01TX_Clinical_WG_Agent_Prioritization_Sub-WG_Summary_RLA.pdf
Accomments:	5050-03-011V_cillical_wg_Agenr_knontrisarion_2nn-wg_2numary_vrw.ha

Dear TX-Clinical Agent Prioritization Subgroup,

I hope you are all doing well today! I know for some of you the pull of the great weather is likely strong to go outside! I hope that you are able to do so despite our scoring task!

Just a quick reminder; please have your score sheets to me by 12pm US ET tomorrow (Sunday, May 3).

In addition, please find attached the summary of yesterday's meeting. Let me know if you have any additions or amendments that you think are critical.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer Research Partnerships

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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura b6 ; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri
	b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike
	b6 Wachtel, Jonathan [jwachtel@deloitte.com]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana b6 ; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative]
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	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose b6 ; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=Exchange Administrative Group (FNIH)
	(FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy b6
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric
	b6; Jansen, Kathrin b6 Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John

b6

Subject:

Summary - CT Capacity WG meeting #5

Attachments: Clinical_Trial_Capacity_Working_Group_Meeting #5_Summary_FINAL.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary of meeting #5 (May 1, 2020) of the full working group. The next full working group meeting is scheduled for Tuesday, May 5 at 9 am eastern time USA.

Best regards,

Karen

Karen H. Tountas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

b6 fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



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b6 ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes ; Diamond, Michael Rose Li b6 ; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi

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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D			
	b6	; Dave Frankowski	b4,b5	; Florence, Clint (NIH/NIAID) [E]
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				2718a-lowyd]
Subject:	April 30 Preclinical	meeting minutes		
Attachments:	s: Antiviral expert names MD PF.docx; 2020-04-30_Preclinical_WG_Summary d3.docx			

Dear Preclinical working group participants,

Please find the minutes from the meeting on April 30th. For ease of review, I have pasted the action items below. In addition, Mike Diamond and Prabha Fernandes have collected potential members of an expert panel for preclinical asset prioritization. The bios for this group have been attached for your review.

Action Items:

- Revise the slides for presentation at the Leadership Meeting. Joe and Rosa to revise, John and Christine to review.
- Prepare slides to describe the proposed NHP strategy for discussion with the NPRC directors on Tuesday, May 5th.
- Small animal team to complete the Table of small animal models and their preferred use for prioritization and presentation to this team next week.
- Send list of Bios for the In Vitro expert panel for review to the full working group, before sending meeting requests from FNIH and Co-chairs. [document included with these minutes, thank you Michael and Prabha for putting this together].

Thank you all for a very interesting and productive meeting. Please provide any comments and suggested modifications to Joe and Rosa.

Sincerely, Joe and Rosa

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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP	
	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]	
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	Vincent, Michael b6 ; Keith Gottesdiener b6 ; Elliott Levy	
	b6 ; Wung, Peter /US b6 ; Koroshetz, Walter (NIH/NINDS) [E]	
	[/o=ExchangeLabs/ou=Exchange Administrative Group	
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner	
	b6	
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative	
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Subject:	Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting	
Attachments:	b4,b5	
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HIACIIV IX-C	linical Prioritization Subgroup members,	
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information. However, I have those and I will include them in the final record for posterity for this round. You can also		
feel free to br	ing them up during the discussion if helpful to the group.	
Thanks,		
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Stacey J. Ac	iam, rnv	
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	b6 ; Wung, Peter /US b6 Koroshetz, Walter (NIH/NINDS) [E]		
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CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative		
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	b6; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];		
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Cubiost:	ACTIV Agant Prioritization Ways 1 Final Discussion Mosting		
Subject:	ACTIV Prioritization Wave 1 Final Discussion Meeting		
Attachments:	ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-Tally.xlsx		
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Start:	5/3/2020 7:00:00 PM		
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Required	Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine		
Attendees:	(NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR);		
	Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs,		
Omtional	Elizabeth (NIH/NIAID) [E]; Carlos O Garner		
Optional	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Salathin, Carla; b6 Parker, Ashley		
Attendees:	(NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E];		
	Ward, Jackie (NIH/OD) [E] b6		

Hi ACTIV TX-Clinical Prioritization Subgroup members,

Please find attached the final tally of scores for the agents that came through triage in Wave 1. We will use this document for our discussions today.

For those who sent me comments, I did not want to over whelm the score sheet will multiple rows of information. However, I have those and I will include them in the final record for posterity for this round. You can also feel free to bring them up during the discussion if helpful to the group.

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Thanks,

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	b6 Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike
	Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];
	Vincent, Michael b6 ; Keith Gottesdiener b6 ; Elliott Levy
	b6 Wung, Peter /US b6 Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner
	b6
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
CC.	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla
	b6 Parker, Ashley (NIH/OD) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	b6 ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject:	RE: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Attachments:	Cytochrome_P450_3A4_and_3A5_Known_Drug_Interaction_Chart.pdf
Fyi- drugs affe	ected by CYP3A4
W	
From: Adam,	Stacey (FNIH) [T] b6
	May 3, 2020 2:31 PM
To: Eric Hughe	
Akli	b6 ; Mellors, John W b6 Naimish Patel b6 ; Colvis,
Christine (NIH	
(FDA/CDER)	
(OS/ASPR/BAF	2DAVCTOS
Gottesdiener	Flight Love William Detay (US)
, <u>l</u>	
(A) (A) (A) (A) (A) (A)	
(NIH/NIAID) [E	\
CC: Elizabeth k	(im <elkim@deloitte.com>; Menetski, Joseph (FNIH) [T] b6 ; Salathin, Carla</elkim@deloitte.com>
l	Parker, Ashley (NIH/OD) [E]
b6	Wholley, David (FNIH) [T] b6 Melencio, Cheryl (FNIH) [T]
b6	Lucas Smalldon b6 Walker, Paula (NIH/NINDS) [E]

b6 ; Ward, Jackie (NIH/NINDS) [E] b6 Subject: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
li ACTIV TX-Clinical Prioritization Subgroup members,
Please find attached the final tally of scores for the agents that came through triage in Wave 1. We will use this locument for our discussions today. For those who sent me comments, I did not want to over whelm the score sheet will multiple rows of information. However, I have those and I will include them in the final record for posterity for this round. You can also seel free to bring them up during the discussion if helpful to the group.
hanks, Itacey
itacey J. Adam, PhD Director, Cancer Research Partnerships Direct: b6 Mobile: b6
oin Zoom Meeting b6
Meeting ID: b6 Password: b6 One tap mobile US (Chicago) US (New York)
Dial by your location US (Chicago) US (New York) US (Germantown) US (Houston) US (San Jose) US (San Jose) US (Tacoma) Meeting ID: b6 Password: b6 Pind your local number: b6

From:	Mellors, John W b6		
Sent:	5/3/2020 8:04:56 PM		
То:	Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes		
	b6 Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group		
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli		
	b6 ; Naimish Patel b6 ; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group		
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John		
	b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group		
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike		
	b6 Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange		
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];		
	Vincent, Michaelb6Keith Gottesdienerb6Elliott Levyb6Wung, Peter /USb6Koroshetz, Walter (NIH/NINDS) [E]		
	b6 \ Wung, Peter /US \ b6 \ Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group		
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth		
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group		
<u> </u>	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner		
cc:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative		
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla		
	b6 , Merritt, Gabriella Marie b6 Romanowski, Jake b6		
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group		
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]		
	[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)		
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group		
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon		
	b6 Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange		
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];		
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group		
Carlo La La	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]		
Subject: Attachments:	RE: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting EMA summary-compassionate-use-remdesivir-gilead_en.pdf		
Attacimients.	EMA summary-compassionate-use-remuesivii-gheau_em.pui		
	h/l		
	b4		
From: Adam.	Stacey (FNIH) [T] b6		
	May 3, 2020 2:31 PM		
To: Eric Hughe			
Akli	es b6 ; Read, Sarah (NIH/NIAID) [E] b6 ; Ruxandra Draghia- b6 ; Mellors, John W b6 Naimish Patel b6 ; Colvis,		
Christine (NIH	I/NCATS) [E] b6 Young, John b6 Stein, Peter		
(FDA/CDER)	b6 Poole, Mike b6 Buchman, Tim		
(OS/ASPR/BÄI			
Gottesdiener	RDA) (CTR) b6 Vincent, Michael b6 Keith b6 Elliott Levy b6 ; Wung, Peter /US 6 Koroshetz, Walter (NIH/NINDS) [E] b6 Higgs, Elizabeth E] b6 Carlos O Garner b6		
b	6 Koroshetz, Walter (NIH/NINDS) [E] b6 Higgs, Elizabeth		
(NIH/NIAID) [I	b6 Carlos O Garner L		
Cc: Elizabeth I	Kim <elkim@deloitte.com>; Menetski, Joseph (FNIH) [1]</elkim@deloitte.com>		
	b6 ; Merritt, Gabriella Marie b6 ; Romanowski, Jake b6		
Parker, Ashley	y (NIH/OD) [E b6 Wholley, David (FNIH) [T] b6 Melencio, Cheryl		
(FNIH) [T]			
[E]	b6		

Hi ACTIV TX-Clinical Prioritization Subgroup members,

Please find attached the final tally of scores for the agents that came through triage in Wave 1. We will use this document for our discussions today.

For those who sent me comments, I did not want to over whelm the score sheet will multiple rows of information. However, I have those and I will include them in the final record for posterity for this round. You can also feel free to bring them up during the discussion if helpful to the group.

Thanks,			
Stacey			
Stacey J. Adam, PhD Director, Cancer Research Partnerships Direct: b6 Mobile: b6			
Join Zoom Meeting			
b6			
Meeting ID: b6 Password: b6 One tap mobile			
b6 US (Chicago) US (New York)			
Dial by your location US (Chicago) US (New York) US (Germantown) US (Houston) US (San Jose) US (San Jose) US (Tacoma) Meeting ID: b6 Password: b6 Find your local number: b6			
Find your local number: b6			

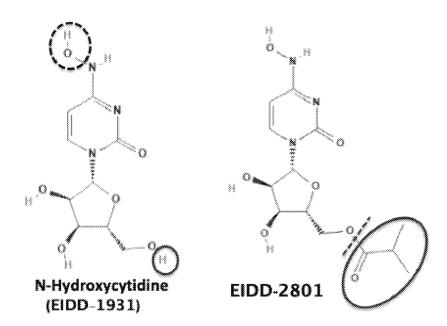
From:	Buchman, Tim (OS/ASPR/BARDA) (CTR) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=00F8A853D8D740F8A8CDD55CBF8EB9DA-TIM.BUCHMAN]			
Sent:	5/3/2020 8:05:36 PM			
To:	Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou	=Exchange Administrative Group		
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd43	-	Adam, Stacey	(FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group	.,	,	, , , ,
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648	859e1cf101c0943414-adamsj4]; Eric	Hughes	
	b6 Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Ad	dministrative G	iroup
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a	1199ae6e0bac2226099-readsa]; Rux	andra Draghia-	Akli
	b6 Mellors, John W [/o=Exchangel	Labs/ou=Exchange Administrative Gr	roup	
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; N	Naimish Patel b6	; Colvis, C	Christine
	(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Admini	strative Group		
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce09845	7896b2df19fa172c87-ccolvis]; Young	g, John	
		o=ExchangeLabs/ou=Exchange Adm		up
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4k	39ba7e62a8d6425f79-Peter.Stein];	Poole, Mike	
	b6 ; Vincent, Michael	b6 } Keith G	ottes diener	
	b 6	; Wung, Peter /US	b6	;
	Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=ExchangeL			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841	.aba16353b96cff8ca9-ehiggs]; Carlos	O Garner	
	b6			
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (F			
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52c			Carla
	b6	Parker, Ashley (NIH/OD)	[E]	
	[/o=ExchangeLabs/ou=Exchange Administrative Group			57
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]			
	[/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)			
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon			
		=-		
	NO .	NIH/NINDS) [E] [/o=ExchangeLabs/ou	_	. 41
	Administrative Group (FYUIBOFFZ3SPULT)/cn=Recipients		132930-walker	p1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]			
Carlo in and		41891e3411cb3a8341-wardjam]		
Subject:	The IV form of EIDD -2801 (N4-hydroxycytidine)			

Please start here:

https://news.emory.edu/stories/2020/02/coronavirus_eidd/index.htm

https://aac.asm.org/content/62/8/e00766-18

The underlying nucleoside is N4-hydroxycytidine ("NHC") which has active concentrations in the nanomolar to low-micromolar range and selectivity indices (SIs) (SI = CC50 [50% cytotoxic concentration]/EC50 [50% effective concentration]) of ≥89 against a broad panel of nasty RNA respiratory viruses.



Timothy G. Buchman, PhD, MD

Senior Advisor

IPA to the DRIVe (Division of Research, Innovation and Ventures)

Biomedical Advanced Research and Development Authority (BARDA)

Office of Assistant Secretary for Preparedness and Response (ASPR)

U.S. Department of Health and Human Services (HHS)

Thomas P. O'Neill, Jr. Federal Building (FOB8)

200 C St SW

Washington, DC 20024

Cell:	b6	
Emai	!:[b6

"Note: This email is intended to provide information and is not to be taken as a directive. If the recipient(s) believe(s) the information provided herein may be construed as a directive, the recipient(s) should disregard that portion of the email."

From: Koroshetz, Wal	ter (NIH/NINDS) [E]	b6			
Sent: Sunday, May 3,	2020 3:42 PM		-		
To: Adam, Stacey (FN			b6		ah (NIH/NIAID) [E]
b6		ı-Akli b 6			
Patel b6		Christine (NIH/NCATS			John
b6		(FDA/CDER)			
b6	; Buchi	man, Tim (OS/ASPR/B	ARDA) (CTR)	b6	; Vincent,
Michael	b6 ; Ke	eith Gottesdiener	b6	Elliott	Levy
b6	Wung, Peter /US	b6	; Higgs, Elizabe	th (NIH/NIAID) [E]
NO	_}; Carlos O Garner	b6			
Cc: Elizabeth Kim <elk< td=""><td>im@deloitte.com>; N</td><td>Menetski, Joseph (FNIH</td><td>) [T] b6</td><td>Salathir</td><td>ı, Carla</td></elk<>	im@deloitte.com>; N	Menetski, Joseph (FNIH) [T] b 6	Salathir	ı, Carla
	b6		Parker, Ashley	(NIH/NCI) [F]	
b6	Wholley, David (FNIH) [T] b6	; Melencio	o, Cheryl (FNIH) [Γ]
b6	Tucas Smalldon	b6	•; W	alker, Paula (NIH	/NINDS) [E]
b6	; Ward, Jackie (N	IH/NINDS) [E]	b6		
Subject: RF: Material	for ACTIV Agent Prior	itization Wave 1 Final	Discussion Meeting	ī	

Fyi- drugs affected by CYP3A4

From: Adam, Stacey (FNIH						
Sent: Sunday, May 3, 2020 To: Eric Hughes	b6		NIH/NIAID) [E]	b6	; Ruxandra	n Draghia
Akli b6	Mellors, Johr	n Wi b6	, Naimish P		i, Nuxariura	: Colvis.
Christine (NIH/NCATS) [E]			, John	h6	Stein, Pete	i′ ′
(FDA/CDER) b		ole, Mike	, 301111 <u>L</u> b6	<u> </u>	Buchman, Tim	•
(OS/ASPR/BARDA) (CTR)			Michael	b6	; Keith	
Gottesdiener	b6	; Elliott Levy	i	: Wung.	Peter /US	
b6		Iter (NIH/NINDS)		b6	Higgs, Elizabet	h
(NIH/NIAID) [E]		rlos O Garner	b6			
Cc: Elizabeth Kim <elkim@< td=""><td></td><td></td><td>FNIH) [T]</td><td>b6</td><td>Salathin, Carla</td><td></td></elkim@<>			FNIH) [T]	b6	Salathin, Carla	
	b6		Parker,	Ashley (NIH/O	·-··	
b6	Wholley, David (I Icas Smalldon	FNIH) [T]	b6 } N	lelencio, Chery		
b6 } Lu	ıcas Smalldon [k	6	Walker, P	aula (NIH/NINDS)	[E]
b6	; Ward, Jackie (NI	H/NINDS) [E]	b 6			
Subject: Material for ACTI	V Agent Prioritiza	tion Wave 1 Fina	Discussion Mee	ting		
Hi ACTIV TX-Clinical Priorit	tization Subgroup	members,				
Please find attached the fidocument for our discussi For those who sent me coinformation. However, I had feel free to bring them up	ions today. Imments, I did not nave those and I w	: want to over wh vill include them i	elm the score sh n the final record	eet will multip	le rows of	
Thanks, Stacey Stacey J. Adam, PhD						
Director, Cancer						
Research Partnerships						
We 7	Mobile: b6	3				
, , , , , , , , , , , , , , , , , , ,	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	<u></u> i				
Join Zoom Meeting		b6				
Meeting ID: b6 Password: b6 One tap mobile						
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Dial by your location 6	(Chicago) (New York) (Germantown) (Houston) (San Jose) (San Jose))				

b6 US (Tacoma)

Meeting ID: b6

Password: b6

Find your local number: b6

From: Mascola, John (NIH/VRC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F78B40A596B4CA4A2850A429D1AE3F2-JMASCOLA]

Sent: 5/4/2020 12:44:44 AM

To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Collins, Francis (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf] Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Tabak, Lawrence (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]

Subject: RE: [EXTERNAL] RE: OK to contact Joe Menetski to discuss opportunities for alignment/ collaboration on ACTIV

activities?

Agree on phase 3 timeline

CC:

That said -	b5	So not sure we can	change their mind. Unlike orphan or low
profit infectious diseas	es;	b5	much more to get
there.			
and Tony of Pfizer's pr	ogress, including which mf	· ·	PP and to stay in close touch with you into advanced development – and their hey do.
Here is more detail:			

This highlights the problem of not creating any disincentive to vaccine developers. The slowest are happy to wait for a master protocol, run by NIH and compare products – as they have nothing to lose. Pfizer, Moderna and JJ – if they are earliest to phase 3, have much less incentive.

How do we deal with this

- We need to be fast, large, adaptive so we have a better phase 3 than anyone else.
- We let each company hold its own IND for phase 3 which means they are in charge of their data, enabling more rapid BLA filing, or EUA by FDA. The data can still be in central database shared with NIH for sure.
- We are flexible on placebo groups and how we share placebo group. One possibility is independent but harmonized phase 3 studies, with shared rolling placebo group. So each company is assured it has a phase 3 study that enables them to get to BLA, and NIH still gets to compare multiple vaccines

Regarding several vaccine formats: he means that BioNTech – the mRNA company that makes the vaccine and has partnered with Pfizer – is testing several mRNA formats, including nucleoside silencing of mRNA (like Moderna) and self-replicating mRNA – using alphavirus replication mechanism to "replicate" many + strand mRNA molecules – allowing more protein to be produced. VRC has tested both formats in NHP, and both work well. So Pfizer will do several phase 1 studies and pick the best one. Moderna has > 10 phase 1 studies – all robustly immunogenic – so we know their format work. BioNTech is a very good mRNA company – so I would be surprised if one of their formats does not work well – but likley, Pfizer will not share the phase 1 until they are ready.

Apologies for long email – may be useful to loop Peter Marks into some of these issues – I think we CAN tackle them as we go – but we absolute need to get initial phase 3 started in July.

From:	Lane, Cliff (NIH/NIAID) [E]	b6					
Sent: S	unday, May 3, 2020 8:36 PM		1				
To: Col	lins, Francis (NIH/OD) [E]	b6]				
Cc: Ma	scola, John (NIH/VRC) [E]	b6	; Fauci, Anth	nony (NIH/NIA	lD) [E]	b6	
Tabak,	Lawrence (NIH/OD) [E]	b6	Parker, Ash	nley (NIH/OD)	[E]	b6	
Subjec activiti	t: Re: [EXTERNAL] RE: OK to cont es?		ki to discuss opp	portunities for	alignment/	collaboration (on ACTIV
I think focus.	we could work with everyone to	get a protocol v	written and read	dy to impleme	ent by the en	d of June with	the right
Cliff							
	On May 3, 2020, at 8:03 PM, Co	ollins, Francis (N	IIH/OD) [E]	b6	wrote:		
	Hi John, Cliff, and Tony,						
	See note below, where Mika vaccine before July. He inter am not quite sure what he m	nds to discuss	our master pro	otocol possib			
	Does this timetable sound re	alistic?					
	Any suggestion about a response	onse?					
	Francis						
	From: Dolsten, Mikael Sent: Sunday, May 3, 2020 6:26 To: Collins, Francis (NIH/OD) [E Subject: Re: [EXTERNAL] RE: Ok collaboration on ACTIV activities	b6 to contact Joe	Menetski to dis	scuss opportur	nities for alig	nment/	
	Hi Francis						
	We certainly enjoy taking part i	n ACTIV					
	I will check if we did get our dru	ugs on the lists b	pelow				
	Concerning the Vaccines maste 2/3 study w our vaccine platfor			-	to a potentia	l pivotal phase	;

We dont want to slow down to wait for a basket trial. I think we have a possible chance to be crossing the finish line way before the time lines shared by JnJ and Sanofi and provide data on a potential safe and effective vaccine in Q3 for Potential use at large scale. I assume the urgency to have an emergency

use or accelerated approval vaccine in USA is priority 1, of its safe and projected effective.

APAR0000001756

I will discuss w Kathrin Jansen if we may have an option to add one of our several vaccine formats that is less advanced or a refined format of our most advanced in the master protocol etc **b4** Happy to discuss w you and welcome your advice Mikael Mikael Dolsten, M.D., Ph.D. Chief Scientific Officer and President, Worldwide Research, Development and Medical Pfizer Inc. 235 East 42nd Street New York, NY 10017 On May 3, 2020, at 5:16 PM, Collins, Francis (NIH/OD) [E] **b6** wrote: Mats Hi Mikael, Thanks for your note and this update on exciting progress on several fronts. ACTIV is moving forward with gratifying speed and commitment. With regard to vaccines, tomorrow the ACTIV vaccines WG will be discussing a master protocol for a phase II/III trial with adaptive design, multiple arms, and a shared placebo arm, aiming to launch on or about July 1. FDA is strongly supportive. The Moderna, Sanofi, and JnJ vaccines are likely to be included – might Pfizer also join? The protease inhibitor sounds really exciting – I trust that compound is on the list of therapeutic candidates that the Clinical Therapeutics WG of ACTIV is reviewing? They are supposed to put forward a tentative list for the Wednesday Leadership Group meeting. Ditto with the b4 option! Looking forward to catching up soon! Best, Francis From: Dolsten, Mikael b6 Sent: Sunday, May 3, 2020 12:06 PM b6 To: Collins, Francis (NIH/OD) [E] Subject: Re: [EXTERNAL] RE: OK to contact Joe Menetski to discuss opportunities for alignment/collaboration on ACTIV activities?

Hi Francis

the difficult Covid times.
In the vaccine space we have progressed rapidly and are already in phase 1/2 studies dose escalation phase testing multiple format of mRNA vaccine b4 b4
In the anti-viral areas we are heading towards IND filing w a first in class potent protease inhibitor broadly inhibiting Coronavirus and very potent on SARSCov2.
We also want to start P2 studies w an b4 b4 I would be keen to know if there are suitable NIH studies for our b4 to tap into , very unique mechanism and we have experience of good safety from phase 2 in RA.
We will soon start a US study at Yale but would be good to tap into additional options, particularly after the failed IL6 mAb, it is suggested that broader or different mechanisms are required for profound clinical effects during advanced Covid at or prior to SARDS stage.
How are things going w ACTIV. Any issues to discuss ?
I hope our PFE representatives in ACTIV are helping out well
Pls let me know if there is anything particular to discuss or I can help you with
Best personal regards Mikael
Sent from my iPhone
On May 3, 2020, at 10:49, Collins, Francis (NIH/OD) [E] b6 wrote:
Hi Morten,
Thanks for your note. It would be great to have this connection — but let me suggest that you start with David Wholley (cc'd here), as he oversees all four of the ACTIV working groups. Joe is the program lead for the group on preclinical therapeutics/repurposing.
Best, Francis
From: Sogaard, Morten ₹ b6 Sent: Sunday, May 3, 2020 10:46 AM To: Collins, Francis (NIH/OD) [E] b6

I trust you are well but likely working too many hours as we all experience in

Cc: Dolsten, Mikael	b6	; Prof Trevor M Jones			
CBE FMedSci	b6	Sogaard, Morten			
b6					
Subject: OK to contact Joe Menetski to discuss opportunities for					
alignment/ collaboration on ACTIV activities?					

Francis,

I hope you are having a good weekend.

Quick question: Would you be OK if I/we reached out to Joe Menetski, who I understand leads many of the ACTIV efforts. We have come to know Joe very well as a great collaborator on the AMP gene therapy initiative and It would be very easy I think working informally with Joe to look a bit more under the hood and identify/ map opportunities for alignment with the other initiatives.

All the Best, Morten

From:	Koroshetz, Walter (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8338DD7CDCD432E986961F1548C5EC6-KOROSHETZW]
Sent:	5/4/2020 1:21:51 AM
To:	Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric
	Hughes b6 Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-
	Akl b6 Naimish Patel b6 Colvis, Christine (NIH/NCATS) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John
	b6 Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike b6 Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];
	Vincent, Michael b6 Keith Gottesdiener b6 Elliott Levy
	b6 Wung, Peter /US b6 Higgs, Elizabeth (NIH/NIAID) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner
	b6
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla
	b6 ; Merritt, Gabriella Marie [GMM76@pitt.edu]; Romanowski, Jake b6
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	b6 ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject:	RE: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Thanks very r	much John. Had a stupid question.
The drug was	s obviously built for HIV which requires activity throughout the body. Has anyone considered whether for
COVID-19 a n	nebulized administration down the trachea into the lung would enable more potent effects given that is the
site of first vi	ral entry? Maybe enable higher doses without untoward effects.
Reason to co	nsider checking this for other anti-virals given in early stages of the illness?
Walter	
From: Mellor	s John W! be
	rs, John W [b6] r, May 3, 2020 4:05 PM
10: Adam, 50	acey (FNIH) [T] b6 ; Eric Hughes 66; Read, Sarah (NIH/NIAID) [E]
L	, realist de la filia de la fi
	ine (NIH/NCATS) [E] b6 Young, John b6 ; Stein, Peter
(FDA/CDER)	
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	b6 Koroshetz, Walter (NIH/NINDS) [E] < b6 Higgs, Elizabeth
(NIH/NIAID) [[E b6 Carlos O Garner b6

Cc: Elizabeth Kim b6 Menetski, Joseph (FNIH) [T] b6 Salathin, Carla	L
t b6 ; Merritt, Gabriella Marie b6 Romanowski, Jake 4 D	6
Parker, Ashley (NIH/OD) [E] b6 Wholley, David (FNIH) [T] b6 ; Mel	encio, Cheryl
(FNIH) [T] b6 Lucas Smalldon b6 Walker, Paula ([E] b6 Ward, Jackie (NIH/NINDS) [E] b6	NIH/NINDS)
[E] b6 Ward, Jackie (NIH/NINDS) [E] b6	
Subject: RE: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting	
b4	
L	
From: Adam, Stacey (FNIH) [T] b6	
Sent: Sunday, May 3, 2020 2:31 PM	
To: Eric Hughes b6 ; Read, Sarah (NIH/NIAID) [E] b6 ; Ruxand	lra Draghia-
Akli b6 Mellors, John W b6 Naimish Patel b6 Christine (NIH/NCATS) [E] b6 Young, John b6 Stein, Pet (FDA/CDER) b6 Proole, Mike b6 Buchman, Tim	; Colvis,
Christine (NIH/NCATS) [E] b6 Young, John b6 ; Stein, Pet	er
(FDA/CDER) b6	
(OS/ASPR/BARDA) (CTR) b6 j, Vincent, Wichael D6 j, Keith	
Gottesdiener b6 Elliott Levy b6 ; Wung, Peter /US	o+h
b6 Koroshetz, Walter (NIH/NINDS) [E] b6 >; Higgs, Elizabeth (NIH/NIAID) [E] b6 Carlos O Garner b6 Carlos O Garner Carlos	etn
Co: Flizabeth Kim celkim@deloitte.com>: Menetski Joseph (FNIH) [T] b6 : Salathin Carla	
Cc: Elizabeth Kim <elkim@deloitte.com>; Menetski, Joseph (FNIH) [T] b6 ; Salathin, Carla b6 Merritt, Gabriella Marie b6 Romanowski, Jake < k</elkim@deloitte.com>	6
Parker, Ashley (NIH/OD) [E] b6 ; Wholley, David (FNIH) [T] b6 Mel	encio. Chervl
(FNIH) [T] b6 Lucas Smalldon b6 Walker, Paula (NIH/NINDS)
[E] b6 Ward, Jackie (NIH/NINDS) [E] b6	, , , , , , , , , , , , , , , , , , , ,
Subject: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting	
Hi ACTIV TX-Clinical Prioritization Subgroup members,	
Please find attached the final tally of scores for the agents that came through triage in Wave 1. We will use document for our discussions today. For those who sent me comments, I did not want to over whelm the score sheet will multiple rows of information. However, I have those and I will include them in the final record for posterity for this round. Ye feel free to bring them up during the discussion if helpful to the group.	
Thanks,	
Stacey	
Stacey J. Adam, PhD Director, Cancer Research Partnerships Direct: b6 Mobile: b6	
Join Zoom Meeting	
b6	
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US (San Jose)
US (Tacoma)

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Password: b6

Find your local number: b6

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF] Sent: 5/4/2020 12:23:24 PM To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras] FW: [EXTERNAL] RE: OK to contact Joe Menetski to discuss opportunities for alignment/ collaboration on ACTIV Subject: activities? Interesting response from Dolsten.... From: Dolsten, Mikael Sent: Monday, May 4, 2020 8:15 AM To: Collins, Francis (NIH/OD) [E] Cc: Fauci, Anthony (NIH/NIAID) [E] Mascola, John (NIH/VRC) [E Lane. Cliff (NIH/NIAID) [E] Lowy, Douglas (NIH/NCI) [E] Jansen, Kathrin b6 Subject: Re: [EXTERNAL] RE: OK to contact Joe Menetski to discuss opportunities for alignment/ collaboration on ACTIV activities? Francis Thanks for the response We appreciate the federal initiative and opportunity to influence it's design. I know Kathrin Jansen (ccd here) from PFE is working w the team on this. We aim to participate in the master protocol in addition to our ongoing trial and will select the most timely vaccine format. It's great to be collaborating w NIH-FDA for the best of our nation and global health. In the master protocol, I hope the working committee is discussing both endpoints, inclusion criteria and prime /booster for sustainability etc . mRNA and protein based vaccines have the opportunity These are just two examples we can discuss on Wednesday in the leadership meeting of times permits .

Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

From:

APAR0000001746

In the therapeutic section , it may be worthwhile to consider what grid for selecting the compounds was used and how did the targets/drugs score . There are a number of scientific and drug development dimensions that seem to predict the probability for a drug to be active . In addition to the strength of the scientific rational , preclinical -clinical/genetic evidence we have seen that outcome of prior clinical trial predicts probability of the next eg is the biology targeted active in human disease and did the specific drug deliver a robust signal . Unfortunately drugs that fail one or two indications have low probability to be successful . There are of course always an exception to any rule :-). I am sure the sub-teams have had rich such dialogues and the leadership meeting can learn or probe in this matter as part of quality review

I look forward to the meeting

Best Mikael Sent from my iPhone

On May 4, 2020, at 04:26, Collins, Francis (NIH/OD) [E] **b6** wrote:

Hi Mikael,

Wow, sounds like you are making fantastic progress with the vaccine program, and we would certainly not want to do anything to slow you down! I understand that you are evaluating several mRNA formats with BioNTech. If one of those turned out to be ready for phase II/III in late June, we would be most interested in the possibility of including that in the master protocol. Please keep Tony and me in touch with Pfizer's progress, including which mRNA format you choose to move into advanced development.

Hope to hear your voice at the ACTIV Leadership Group meeting on Wednesday. There will be a lot to talk about!

Best, Francis

From: Dolsten, Mikael | b6

Sent: Sunday, May 3, 2020 6:26 PM

To: Collins, Francis (NIH/OD) [E] | b6

Subject: Re: [EXTERNAL] RE: OK to contact Joe Menetski to discuss opportunities for alignment/

collaboration on ACTIV activities?

Hi Francis

We certainly enjoy taking part in ACTIV

I will check if we did get our drugs on the lists below

Concerning the Vaccines master protocol, by July we will hopefully be far into a potential pivotal phase 2/3 study w our vaccine platform and its most advanced candidates.

We dont want to slow down to wait for a basket trial. I think we have a possible chance to be crossing the finish line way before the time lines shared by JnJ and Sanofi and provide data on a potential safe and effective vaccine in Q3 for Potential use at large scale. I assume the urgency to have an emergency use or accelerated approval vaccine in USA is priority 1, of its safe and projected effective.

I will discuss w Kathrin Jansen if we may have an option to add one of our several vaccine formats that is less advanced or a refined format of our most advanced in the master protocol etc

If we can agree about shared key endpoints, we can include that cross all studies Whether master protocol or more advanced sponsor trials which helps comparison

Happy to discuss w you and welcome your advice Mikael

Mikael Dolsten, M.D., Ph.D. Chief Scientific Officer and President, Worldwide Research, Development and Medical Pfizer Inc. 235 East 42nd Street New York, NY 10017

On May 3, 2020, at 5:16 PM, Collins, Francis (NIH/OD) [E] **b6** wrote: Mats

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The protease inhibitor sounds really exciting – I trust that compound is on the list of therapeutic candidates that the Clinical Therapeutics WG of ACTIV is reviewing? They are supposed to put forward a tentative list for the Wednesday Leadership Group meeting. Ditto with the **b5** option!

Looking forward to catching up soon!

Best, Francis

From: Dolsten, Mikael b6
Sent: Sunday, May 3, 2020 12:06 PM
To: Collins, Francis (NIH/OD) [E] b6

Subject: Re: [EXTERNAL] RE: OK to contact Joe Menetski to discuss opportunities for

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Best, Francis	
From: Sogaard, Morten < b6 Sent: Sunday, May 3, 2020 10:46 AM To: Collins, Francis (NIH/OD) [E] b6	

Cc: Dolsten, Mikael	b6	Prof Trevor M Jones			
CBE FMedSci ←	b6	Sogaard, Morten			
b6					
Subject: OK to contact Joe Menetski to discuss opportunities for					
alignment/ collabora	ation on ACTIV activities?				

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All the Best, Morten

From:	(FYDIBOHF23SPDL	T)/CN=RECIPIEN			ISTRATIVE GROUP 101C0943414-ADAM	SJ4]
Sent:	5/4/2020 1:35:57					
Го:	Bozzette, Sam (NII	H/NCATS) [E] [/o	=ExchangeLabs/d	ou=Exchange Adm	inistrative Group	
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	(NIH/NIAID) [E] [/c	b6	•			, Froschaff, Michael
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					257a1802-shenyu.fda	a]; Farley, John (FDA/CDER)
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	[E] [/o=ExchangeLa					
				e0f42f897d1294cf	bb99c10-goffdc]; Vin	cent, Michael
	b6	; Wı	ung, Peter /US	b6	Karen Lynn P	rice
	b6	Pam	nela Tenaerts, M.	D. [pamela.tenaer	ts@duke.edu]; Koro	shetz, Walter (NIH/NINDS)
	[E] [/o=ExchangeLa	abs/ou=Exchang	e Administrative	Group		
	(FYDIBOHF23SPDL	T)/cn=Recipient	s/cn=e8338dd7c	dcd432e986961f1	548c5ec6-koroshetzv	v]
CC:	Mary Biggs	b6	; Demarcus	b6	; Macone, Erin	b6
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	[jwachtel@deloitte	e.com]; Elizabetl	h Kim [elkim@de	loitte.com]; Parke	r, Ashley (NIH/OD) [E	[]
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Dear TX-Clinical Master Protocol Subgroup,

Please find attach the materials for today's meeting.

- 1. Agenda
- 2. Slides

Thanks,

Stacey J. Adam, PhD Director, Cancer Research Partnerships Direct: [|| Mobile: b6 Join Zoom Meeting b6 Meeting ID: b6 Password: **b6** One tap mobile US (Chicago) b6 US (New York) Dial by your location US (Chicago) US (New York) US (Germantown) US (San Jose) US (San Jose) US (Tacoma) US (Houston) Meeting ID: b6

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Stacey

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Required Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo Attendees: (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Koroshetz, Walter (NIH/NINDS) [E] Optional Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T] Dear TX-Clinical Master Protocol Subgroup, Please find attach the materials for today's meeting. 1. Agenda 2. Slides Thanks, Stacey Join Zoom Meeting b6 Meeting ID: b₆ Password: One tap mobile US (Chicago) **b6** US (New York) Dial by your location US (Chicago) US (New York) US (Germantown) US (San Jose) US (San Jose)

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Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo

(FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne

Required

Attendees:

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(FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Koroshetz, Walter

(NIH/NINDS) [E]

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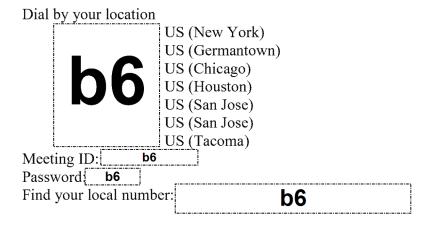
Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley

Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

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	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla
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	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject:	Follow-up from ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Attachments:	2020-05-03_TX-Clinical_WG_Agent_Prioritization_Subgroup_Summary.pdf

Hi ACTIV TX-Clinical Prioritization Subgroup members,

Thank you all once again for a very productive meeting yesterday, and especially thank for the extra hour and a half that you gave to the discussion. I appreciate that you helped us get to a good set of selections for our first round and that you helped us learn a lot about how to refine the process.

Please find attached the official summary of yesterday's call. Please let me know if you feel and additions or amendments are needed to accurately reflect the record of our discussions. Please keep in mind that this will be the official record of our first meeting, so review with that eye for any necessary details.

We will send the materials out for tomorrow's call tomorrow AM, but the main focus of our call will be to debrief on our final review meeting and suggestions for improving the next round.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships
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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] 5/5/2020 1:58:10 AM Sent: To: Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike b6 ; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Bascles, Lionel b6_______; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King.]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura b6 b6; Wachtel, Jonathan [jwachtel@deloitte.com]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm] CC: Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Kenny, Dermot **b6**; Anderson, Margaret [marganderson@deloitte.com]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject:	ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments:	Clinical Trial Capacity Working Group Meeting Agenda_05052020.pdf; Network survey responses 04 May 2020.pdf;
	Site survey responses 04May2020.pdf; DRAFT CRO survey.docx
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necurrence.	every Tuesday and Friday from 9:00 AM to 10:00 AM
Required	Stein, Peter (FDA/CDER); Vincent, Mike; Woodcock, Janet (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Bascles, Lionel;
Attendees:	Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura
	Srinivasan, Badhri; Wachtel, Jonathan; Qashu, Felicia
Optional	Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Anderson, Margaret; Colvis, Christine (NIH/NCATS) [E]; Hughes,
Attendees:	Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T];
	Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b6 ; Francis Collins; Gonzalez, Nina; Heaton, Penny;
	James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David
	(FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] b6 ;
	Thomas, Ashley (FDA/CDER); Stratton, Benjamin; Tolman, Brett; Garner, Carlos; Davey, Victoria; Jintanat
	Ananworanich
Dear Colleagu	ies,
Attached is th	e meeting agenda along with current survey results b5. In addition,
attached are d	raft questions to consider for the CRO survey that will be discussed, but please note that some questions are
	rom the network survey for consideration (editing or deleting). Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

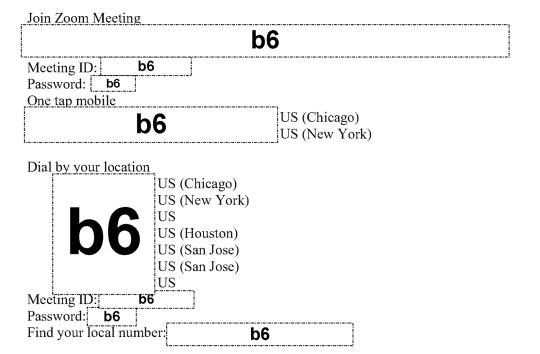
Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards, Karen

Karen H. Tountas, PhD Scientific Program Manager Foundation for the National Institutes of Health



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/5/2020 2:26:19 AM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner ; Eric Hughes Keith Gottesdieneri Amanda Peppercorn b6 Proschan, Michael Menon (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael Wung, Peter /US b6 Karen Lynn Price; Pamela Tenaerts, M.D. b6 Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw] CC: Mary Biggs b6 Demarcus b6 Macone, Erin Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Chertow, Jessica (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=742e0637f5da45aa9bde0d9de07a80d8-chertowjh]; Paltoo, Dina (NIH/NLM) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afbb60a3cbed495aa92790a75dc3ffd6-paltood]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh] Subject: Follow-up to ACTIV TX-Clinical Master Protocol Subgroup Meeting #12

Attachments: ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 12_Key Takeaways_05042020.pdf

Dear TX-Clinical Master Protocol Subgroup and Invited Guests,

Thank you all for a very productive meeting today! We want to especially thank our NHLBI/NINDS colleagues that came into speak with us about their master protocol that they have been working to launch the last few weeks. The information was most helpful for our discussions. We appreciate you taking the time.

As usual, please find the high level quick summary and action items from our meeting today. For the benefit of our guests, we take just a quick high level running summary versus a formal meeting write-up for these meetings, since try to turn it around the same day.

Please let me know any amendments or additions you may wish to note for us to make.

Again, thank you all for joining us. We look forward to close collaboration between our two groups.

Thanks, Stacey

Stacey J. Adam, PhD Director, Cancer Research Partnerships

Research Partnerships
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Dear TX-Clinical Master Protocol Subgroup members,

For the meeting that we have set tomorrow, we will be using the same slides from today since we did not get a chance to full finish our discussion. (Attached again here for you reference. The agenda slide will be updated for tomorrow.)

Tomorrow will be a pretty heavy stats and protocol design discussion so please come prepared to think through our options.

As food for thought if we do decide to move in the direction of a factorial design, I am attaching here the RECOVERY protocol from the UK, which uses a complex design such as this and is a large confirmatory style trial such as that we are considering. This may not be exactly what we need, but it could be a counterpoint to the ACTT-2 protocol that we have been evaluating and which I attach again here for ease of reference. Keep in mind that either option we choose will require modification for our purposes. We have already begun this for the ACTT protocol, but we may be able to incorporate additional design ideas from others.

I look forward to a very productive discussion tomorrow. Thank you for being willing to meet between our normally scheduled meetings.

Thanks, Stacev

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Stacey J. Adam, Ph	D				
Director, Cancer					
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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR] 5/5/2020 6:43:36 AM Sent: ; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; **b6** IN USARMY MEDCOM WRAIR (USA) **b6** Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56fdbe4598a57b423d484dcf9f-offit.email]; b6 Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccba4e3caaf5eb5d3586b1cc-Jonathan.Se]; Tal Zaks [CC: Tolman, Brett [btolman@deloitte.com]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Douoguih, Macaya ; Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Gilbert PhD, Peter Paul Gillard h; Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda]; Gurunathan, Sanjay Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamil]; j; Ledgerwood, Julie (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dc9f31ded594eff8ac506d2c4103c15-ledgerwood]; Leyssen, Maarten Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som]; Robb, Merlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17bbdb1e858542e7b5959ec7aeb7679a-mrobb.hivre]; b6 Michael Watson (x) ; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject: Agenda and Materials for ACTIV Vaccines Working Group meeting: Today, 5 May

Attachments: 2020-05-05 Vaccines Working Group Visuals.pptx; ACTIV Vaccines Clinical Trials Sub-Group roster - 4 May 2020.docx;

2020-05-04 Vaccines Clinical Trials Sub-Group meeting Notes.docx

Dear Vaccines Working Group,

We are looking forward to our next Vaccines Working Group meeting with you, today (Tuesday) at 12pm ET (9am PT / 6pm CEST). The key agenda items for our meeting are:

- Review new mandates for the Working Group
- Discuss pathways to approval/authorization using correlates and other evidence
- Share ACTIV external communications approach

The slides that we will use during the meeting are attached, with some additional slides drawn from the presentation Marion Gruber shared (attached in full in Friday's notes) in an appendix for reference.

We also want to share an update related to the first agenda item. The Vaccines Clinical Trials Sub-Group met for the first time yesterday (Monday). Much as we anticipate the master protocol trial doing, we rapidly enrolled participants (though perhaps with limited informed consent) in this Sub-Group; the roster as of today is attached, with some additional invitations pending. We have also attached the notes from that meeting.

As always, please do not hesitate to reach out with any input or questions.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T] Sent: Sunday, May 3, 2020 5:45 PM

Subject: Vaccines Working Group important update: Clinical Trial plans

Dear Vaccines Working Group,

Yesterday evening there was an exciting expansion of the opportunity for the Vaccines Working Group to contribute to accelerating vaccine development. We learned that there will be US government funding for a master protocol phase 2/3 adaptive vaccine efficacy trial, with provisions to add and drop vaccine candidate arms over time.

The Clinical Trial Sub-Group (slight name change) will be tasked with supporting this master protocol trial, including the protocol and the networks/sites implementation. The goal is to have this trial ready to start by July 1, though there may be an opportunity to start in June if the work can be completed by then.

This is a significant expansion of scope for the Sub-Group. Given the magnitude of this responsibility, we will be asking for additional representation on the Sub-Group and pulling in expertise, including some of the master protocols experts that have been writing the ACTIV therapeutics protocols. The first meeting of the Sub-Group is tomorrow at 10am ET (7am PT / 4pm CEST).

We will also discuss this at the Vaccines Working Group meeting on Tuesday at 12pm ET (9am PT / 6pm CEST). Please don't hesitate to reach out with any questions.

Best regards,

Mike, for the Vaccines Working Group

Michael Santos, PhD

Associate Vice President, Science

Foundation for the National Institutes of Health

b6 fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP] Sent: 5/5/2020 11:56:17 AM To: /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group CC: (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Diamond, Michael ; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy ; Jansen, Kathrin Hughes, Eric b6 ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, ; Rose Li Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes j; Dana Carluccio Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D Dave Frankowski]; Baric, Toni C b6]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd] Subject: Canceled: ACTIV Preclinical working group (Tuesday meeting) Location: Start: 5/5/2020 6:00:00 PM 5/5/2020 7:00:00 PM End: Show Time As: Free Recurrence: Weekly every Tuesday from 2:00 PM to 3:00 PM Required **b6** Attendees: b6 Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas Optional Florence, Clint (NIH/NIAID) [E]; Diamond, Michael; Gonzalez, Nina; Wholley, David (FNIH) [T]; Austin, Christopher Attendees: (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E] Cancelling due to the NPRC director's meeting. Joseph Menetski is inviting you to a scheduled Zoom meeting. Join Zoom Meeting b6 Meeting ID: b6 Password: One tap mobile US (Chicago) **b6** US (New York) Dial by your location US (Chicago) US (New York) US (Houston) US (San Jose) US (San Jose) US Meeting ID: b6 Password: **b6** Find your local number: b6

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To:	Eric Hughes b6; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
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	Vincent, Michael b6 ; Keith Gottesdiener b6 ; Elliott Levy
	b6 ; Wung, Peter /US b6 ; Koroshetz, Walter (NIH/NINDS) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
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CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla b6
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
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	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
Codelinate	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Attachments:	Materials for ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #7 ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting 05May2020 Agenda.pdf; ACTIV Therapeutics-
Attacimients.	Clinical_AP Subgroup_4May2020 Meeting Guide.pdf
	Cirrical_Ar Subgroup_4Way2020 Weeting Guide.pur
Dear TX-Clinic	al Agent Prioritization Subgroup,
Dear 17 dinne	ar Agent Frontization Subgroup,
Please find at	tached the materials for today's meeting. My apologies for the late distribution.
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Thanks,	
Stacey	
Stacey	
Stacey J. Ad	am. PhD
Director, Can	
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Sent: To:	5/5/2020 4:02:38 PM Eric Hughes
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla b6
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	[/o=ExchangeLabs/ou=Exchange Administrative Group
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	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	b6 ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Calling	ACTIVITY Clinical Annua Deignitication Collegen Manating 47
Subject:	ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #7
Attachments:	ACTIV Therapeutics-Clinical_AP Subgroup_4May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical_Agent
· · · · · · · · · · · · · · · · · · ·	Prioritization Sub-Group Meeting 05May2020 Agenda.pdf
Location:	b6
Start:	5/5/2020 5:00:00 PM
End:	5/5/2020 6:00:00 PM
Show Time As:	
Show Time As.	rentative
Required Attendees:	Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs,
	Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla b6
Attendees:	Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] b6

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for today's meeting. My apologies for the late distribution.

Thanks,
Stacey

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From:	Wung, Peter /US b6
Sent: To:	5/5/2020 5:50:49 PM Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes
	b6 Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Patel, Naimish /US b6 Colvis,
	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];
	Vincent, Michael b6 ; Keith Gottesdiener [keith.gottesdiener@gmail.com]; Elliott Levy
	b6 ; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner
	b6 Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	Maria [rosalvarez@deloitte.com]; Salathin, Carla [carla.salathin@novartis.com]; GMM76@pitt.edu; JKR31@pitt.edu; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
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	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject:	RE: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #7
Attachments:	Coagulopathy COVID Blood Apr 2020.pdf
Dear All:	
This is really e	excellent review article in the current understanding of coagulopathy in COVID-19.
Regards,	
Peter	
-	ppointment
	Stacey (FNIH) [T] b6
	ay, April 30, 2020 7:55 AM
	acey (FNIH) [T]; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; Mellors, John W; Patel, Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim
	RDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter
	[E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
	Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; b6
	y (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula
(MIH/MIMDS)	[F]: Ward Tackie (NIH/NINDS) [F]

When: Tuesday, May 5, 2020 1:00 PM-2:00 P	
Where:	b6
EXTERNAL : Real sender is b6	
Dear TX-Clinical Agent Prioritization Subgrou	p,
Please find attached the materials for today's	s meeting. My apologies for the late distributio
Thanks, Stacey	
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Cana	•	• •	ITS/CN=DCD875F06796488	59E1CF101C094	43414-ADAMSJ4J
Sent: To:	5/5/2020 11:14: Eric Hughes		LaVange, Lisa M	b6	; Sandeep Menon
cc:	Administrative G Karen Lynn Price Pranab Group (FYDIBOH Demarcus Groekenselal (FYDIBOHF23SPI [/o=ExchangeLal (FYDIBOHF23SPI [T] [/o=Exchange	b6 b6 F23SPDLT)/cn=Re b6 ps/ou=Exchange A DLT)/cn=Recipient ps/ou=Exchange A DLT)/cn=Recipient	Proschan, Michael (NIH/NI 3SPDLT)/cn=Recipients/cn= Le Corre, Chri Read, Sarah (NIH/NIAID) cipients/cn=527b16003800 ; Elizabeth Kim [elkim@dministrative Group s/cn=306b2244466140faa9ddministrative Group	AID) [E] [/o=Exc -7b45059209b4 stophe [] [E] [/o=Exchan :4a199ae6e0bac deloitte.com]; :5aaaafe06ebd7	hangeLabs/ou=Exchange 468bb4ba02b0dfbbb3e4-proscham]; b6
Subject: Location:	ACTIV TX-Clinica	Master Protocol	Subgroup Meeting #13 - Sta b6	ats ONLY - HOLE)
Start:	5/6/2020 3:00:0	0 PM			
End:	5/6/2020 4:00:0	0 PM			
Show Time As:	Tentative				
Required Attendees: Optional Attendees:	Christophe; Gho	sh, Pranab; Read,	Sarah (NIH/NIAID) [E]		E]; Karen Lynn Price; Le Corre, [T]; Melencio, Cheryl (FNIH) [T]
Dear TX-Cli	nical Master P	rotocol Subgro	up Stats Group,		
simulation m	nodeling. Seco eting at 2-3pm, We are moving	nd, due to some so right now it	e time conflicts for esse looks like we have the	ential membe largest quori	talk statistical design and rs of this group, we could not um for 11am-12pm ET e's calendar while we confirm al
Thanks,					
Stacey					
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US (Chicago)
US (San Jose)
US (Tacoma)
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US (San Jose)

Meeting ID: b6

Password: b6

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]

Sent: 5/6/2020 1:28:28 AM

To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]

Subject: RE: news and question

Yes! I spoke with Ruxandra, and they are indeed willing to shift the JnJ plans for infliximab, now preferring to have it included in ACTT-3 instead of going their own way. I was delighted. I'm looping in Stacey – does the WG need to re-confirm their 11.3 vote in order for this to be presented tomorrow, or can this be considered a done deal?

FC

From: Wholley, David (FNIH) [T]	b6	
Sent: Tuesday, May 5, 2020 8:55 PM		··-·
To: Collins, Francis (NIH/OD) [E]	b6	
Subject: RE: news and question		i

Subject. NE. Hews and question

From what I hear it is likely good news. J&J is willing to put the trial they were planning for infliximab (Remicade), one of the immune modulators the Tx-Clinical Agent Prioritization Sub Group has put near the top of their list for ACTIV, on hold despite its being well through planning with FDA, in favor of putting it into the "ACTIV ACTT-3" protocol we are proposing to launch. She has discussed it with Mattai Mammen who makes these kinds of decisions. Don't know whether Paul Stoffels has been told yet. So what I strongly recommend you do: take the call, play dumb, and be absolutely delighted.

(Hope that is indeed what this turns out to be!)

From: Collins, Francis (NIH/OD) [E] **b6**Sent: Tuesday, May 5, 2020 7:30 PM

To: Wholley, David (FNIH) [T] **b6**Subject: FW: news and question

Importance: High

Any idea what this might be about?

From: Draghia Akli, Ruxandra [JRDUS] b6
Sent: Tuesday, May 5, 2020 6:14 PM
To: Collins, Francis (NIH/OD) [E] b6
Subject: news and question

Importance: High

Dear Francis – this world is getting smaller ③ it is really great to be able to join forces on COVID. Another example of "all hands on deck" and undertaking something meaningful, with a tremendous impact on global health.

Would it be possible to have a short chat rapidly? I do have some news, and would like to get your feedback, if possible.

Kind regards, Rux

Ruxandra Draghia-Akli, MD, PhD

Global Head Global Public Health R&D



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	[/o=ExchangeLabs/ou=Exchange Administrative Group					
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	b6 ; Keith Gottesdiener b6 Eric Hughes					
	b6 ; LaVange, Lisa M b6 ; Elliott Levy b6 ; Sandeep					
ı	Menon b6 ; Amanda Peppercorn b6 ; Proschan, Michael					
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group					
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	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group					
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	b6 ; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group					
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	[/o=ExchangeLabs/ou=Exchange Administrative Group					
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	Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group					
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	[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]					
	[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina					
	b6 ; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group					
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Subject:	Follow-up from ACTIV TX-Clinical Master Protocol Ad Hoc Meeting					
Attachments:	ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting_Key Takeaways_05052020.pdf					
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Dear TX-Clinical Master Protocols Subgroup,

Please find attached the quick capture summary and action items from our meeting today. If you have any additions or amendments, don't hesitate to let us know.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

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	Christine (NIH/NCATS) [E]					
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	Maria [rosalvarez@deloitt				b6	701 02) 11030
	Parker, Ashley (NIH/OD) [E	•••	L	dministrative Gro	oup	
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Subject:	Follow-up from ACTIV TX-0	_		_		
Attachments:	ACTIV_Therapeutics-Clinic				20.pdf; 2020-05-03_T	.X-
	Clinical_WG_Agent_Priorit	ization_Subgroup_	Summary-Ameno	ded.pdf		

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached a quick summary of the action items and suggestions for improvement in the review process that Elizabeth was kind enough to capture for us today. While I will send out the official summary, I thought it might be beneficial for you all to have this today.

In addition, please find attached the modified summary from our final prioritization meeting for Wave 1 with additions from some of you captured.

Thanks, Stacey

Stacey J. Adam, PhD Director, Cancer

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То:	Eric Hughes b6; LaVange, Lisa M b6; Sandeep Menon						
	Eric Hughes b6 LaVange, Lisa M b6 Sandeep Menon						
CC:	Demarcus b6 ; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]						
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Subject: Attachments:	ACTIV TX-Clinical Master Protocol Subgroup Meeting #13 - Stats ONLY						
Location:	ACTIV Therapeutics-Clinical_MP Subgroup_6May2020 Meeting Guide.pptx b6						
Start:	5/6/2020 3:00:00 PM						
End:	5/6/2020 4:00:00 PM						
Show Time As:	Tentative						
Required Attendees: Optional Attendees:	Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Karen Lynn Price; Le Corre, Christophe; Ghosh, Pranab; Read, Sarah (NIH/NIAID) [E] Demarcus; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]						
Hi All,							
Confirming t	his meeting and attaching just some slides that might help us tomorrow.						
Thanks,							
Stacey							

Dear TX-Clinical Master Protocol Subgroup Stats Group,

First, we have decided to limit this meeting just to this smaller group to really talk statistical design and simulation modeling. Second, due to some time conflicts for essential members of this group, we could not keep the meeting at 2-3pm, so right now it looks like we have the largest quorum for 11am-12pm ET tomorrow. We are moving the meeting to this time and holding it on everyone's calendar while we confirm all attendees availability.

Thanks,

Stacey

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	b6 Garner, Carl b6 Higgs, Elizabeth (NIH/NIAID) [E]						
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	[elkim@deloitte.com]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Hughes, Eric						
	b6						
Subject:	News from ACTIV Leadership						

Dear TX-Clinical Working Group,

We wanted to let you know some news that was shared with us by the ACTIV Leadership Team.

In order to begin to show the field a unified plan and messaging for the testing of therapeutics for COVID-19 under ACTIV, the ACTIV Leadership has decided to bring into the program both the NIAID ACTT-2 Trial evaluating baricitinib and another NIAID master protocol evaluating IVIg and add these protocols to the portfolio of ACTIV Master Protocols. The ACTIV leadership is aware that our agent prioritization group think both the JAK/STAT inhibitors and IVIg are important to test, but knows we did not initially select them due to the development of these parallel trials. NIAID has already been working to ensure harmonization between these trials as we have with ACTT-3, so it was felt that these would be a natural fit to complement our efforts.

We are excited that our work is being recognized not only for ACTT-3, but also helping to promote further alignment and unity in the field.

Thank you all for all your efforts so far!

Sarah, Eric, and Stacey

Stacey J. Adam, PhD

Director, Cancer

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Sent:	5/6/2020 7:29:07 PM					
Sent: To:	Bascles, Lionel b6 ; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry b6 ; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers , Betsy b6 ; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos b6 ; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe					
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CC:	Criffield, Robin b6 ; Hamilton, Nancy b6 ; Melencio, Cheryl					
	(FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group					
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	[marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group					
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	b6 Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative					
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	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li,					
	Rose b6 Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative					
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	Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine					
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	b6 Jansen, Kathrin b6 ; Lowy, Douglas (NCI)					
	[/o=ExchangeLabs/ou=Exchange Administrative Group					
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)					
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group					
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	b6					
į						

Subject: Summary and action items - CT Capacity WG meeting #5

Attachments: Clinical_Trial_Capacity_Working_Group_Meeting #6_Summary_Final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #6 (May 5, 2020) of the full working group. The next full working group meeting is scheduled for Friday, May 8 at 9 am eastern time USA.

Best regards, Karen

Karen H. Tountas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

b6 fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

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Sent: To:						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]					
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa					
	Maria [rosalvarez@deloitte.com]; Salathin, Carla					
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]					
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	b6 ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange					
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	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group					
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Subject:						
Attachments:						
Dear TX-Clinic	al Agent Prioritization Subgroup,					
Please find at amendments.	tached the formal summary from yesterday's meeting. Please let me know if you have any additions or					
Thanks, Stacey						
Stager V A.I.	on DLD					
Stacey J. Ada Director, Can						
Research Part						
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Direct:	Foundation for the National Institutes of Health Direct: b6 Mobile: b6					
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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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	Ruxandra Draghia-Akli b6; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel b6 Colvis,
	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike
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	Vincent, Michael b6 ; Keith Gottesdiener b6 ; Elliott Levy b6 j; Wung, Peter /US b6 j; Koroshetz, Walter (NIH/NINDS) [E]
	b6]; Wung, Peter /US b6]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	b6 ; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
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	Maria [rosalvarez@deloitte.com]; Salathin, Carla b6
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	b6 Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject:	Materials for ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #8
Attachments:	
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	omited_A Subfroup_/May2020 Meeting Suide.pur
Dear TX-Clinio	cal Agent Prioritization Subgroup,
Dear TX ellill	sair igent i mornization sabgi sap)
We are lookir	ng forward to our meeting tomorrow during which we will work to flesh out some of our suggestions for
	ts in the prioritization process a bit more. We will also talk about next steps over the rest of this week and
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Dlagge find at	tacked the agenda and clides for temorrow's meeting. If you have any additions or amendments, please
	ttached the agenda and slides for tomorrow's meeting. If you have any additions or amendments, please
let me know.	
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Thanks,	
Stacey	
Stacey J. Ad	
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Join Zoom Meeting **b6** Meeting ID: Password: **b6**One tap mobile US (New York) **b6** US (Germantown) Dial by your location US (New York) US (Germantown)
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US (Houston) US (San Jose) US (San Jose) US (Tacoma) Meeting ID: b6 Password: **b6**Find your local number: b6

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Subject: Attachments:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam] ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #8 ACTIV Therapeutics-Clinical_AP Subgroup_7May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical_Agent					
Landing	Prioritization Sub-Group Meeting 07May2020 Agenda.pdf					
Location:	b6					
Start: End: Show Time As:	5/7/2020 5:00:00 PM 5/7/2020 6:00:00 PM Tentative					
Required Attendees:	Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]					
Optional	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; b6					
Attendees:	Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] b6					

Dear TX-Clinical Agent Prioritization Subgroup,

We are looking forward to our meeting tomorrow during which we will work to flesh out some of our suggestions for improvements in the prioritization process a bit more. We will also talk about next steps over the rest of this week and next.

Please find attached the agenda and slides for tomorrow's meeting. If you have any additions or amendments, please let me know.

Thanks, Stacey Join Zoom Meeting **b6** Meeting ID: b6 Password: **b6** One tap mobile US (New York) **b6** US (Germantown) Dial by your location US (New York) US (Germantown) US (Chicago) US (Houston) US (San Jose) US (San Jose) US (Tacoma) Meeting ID: **b6** Password: b6 Find your local number: b6

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b6 Jansen, Kathrin b6 Kurilla, Michael (NIH/NCATS) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group

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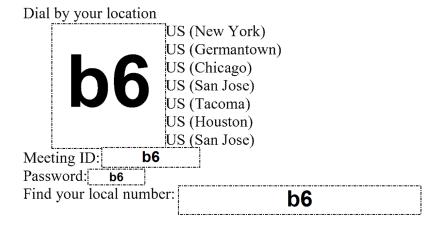
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		ts/cn=user3c2f486d]; Dana Carluccio	b6	; Rose	
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Smalldon b6 ; Stratton, Benjamin [bstratton@DELOITTE.com]; jennifer.j.palmer@pfizer.com; Mollica, Linda /US b6 ; Qashu, Felicia (NIH/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group					
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Subject:	Material for ACTIV TX-Clinical Wo	-			
Attachments:		May2020 Meeting Guide.pdf; ACTIV Thera	apeutics-Clinical WG 7May202	20	
	Agenda.pdf				
Dear TX-Clinio	cal Working Group and Invite Gu	uests,			
		eeting tomorrow. We will have both the			
-		nd the co-chairs will provide a quick u	pdate from the ACTIV Lead	lership	
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	_	elected for by the Agent Prioritization			
	participation is discussed with t	the companies, so we would ask that	you not snare these outsic	ie the	
group.					
Thanks,					
Stacey					
Stacey J. Ad	am. PhD				
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/7/2020 2:11:32 AM Sent: To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra b6 ; Eisner, Mark b6 ; Gottesdiener, Keith b6 ; Hughes, Eric b6 ; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep **b6** Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish b6 ; Peppercorn, Amanda b6 ; Proschan, Michael (NIH/NIAID) [E] [/o=Exchange abs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn b6 ; Garner, Carl b6 Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy b6); Jansen, Kathrin (b6); Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group
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	Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
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	Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas
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Subject:	ACTIV TX-Clinical Working Group #5
Attachments:	ACTIV Therapeutics-Clinical WG 7May2020 Meeting Guide.pdf; ACTIV Therapeutics-Clinical WG 7May2020
	Agenda.pdf
Location:	b6
Start:	5/7/2020 6:00:00 PM
End:	5/7/2020 7:00:00 PM
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Attendees:	Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John;
	Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael
	Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs,
	Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]
Optional	Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas
Attendees:	(NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla;
	Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman,
	Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon;
	Stratton, Benjamin; b6 ; Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy
	(NIH/NHLBI) [E]
Dear TX-Clinic	cal Working Group and Invite Guests,
	tached the materials for our meeting tomorrow. We will have both the Agent Prioritization and Master
_	groups discuss ongoing efforts and the co-chairs will provide a quick update from the ACTIV Leadership
meeting yeste	erday.
	hat the drugs that have been selected for by the Agent Prioritization team are still being held internal to
•	participation is discussed with the companies, so we would ask that you not share these outside the
group.	
Thanks,	
Stacey	
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Subject:

REVIEW REQUESTED: Covid-19 human challenge model perspective outline; also Vaccines WG meeting notes Attachments: SARS-CoV-2 Controlled Human Infection Model in Support of Preventive Vaccines Outline.docx; controlled human infection model references.zip; 2020-05-05 Working Group meeting Summary Notes.docx

Dear Vaccines Working Group (and cc'ing other Sub-Group members),

Thank you for your participation in yesterday's Vaccines Working Group meeting. Summary notes kindly prepared by the science writer that supports our group are attached. If you have any additions or edits, please feel free to pass them along.

As we discussed at the meeting, an important new deliverable for our Working Group is a perspective on the scientific and operational obstacles for developing a COVID-19 human challenge model on a relevant timescale. A small team from the Vaccine Clinical Trials Sub-Group has taken on that responsibility, with our gratitude.

Please review the attached outline. The team has a particular question about how much substantiation of the points being made is necessary. The team is also contemplating which audiences to target and the best ways to reach them. If you have suggestions or feedback on the outline, or perspectives on these questions, please share them with us. Existing papers on this topic are attached in the zip file for your reference. This will be an important agenda topic at our next Working Group meeting on Monday, May 11, 12pm ET (9am PT / 6pm CEST).

We look forward to continued engagement as we forge ahead on the path to support accelerated vaccine development. Please reach out anytime with questions or suggestions.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T] Sent: Tuesday, May 5, 2020 2:44 AM

Subject: Agenda and Materials for ACTIV Vaccines Working Group meeting: Today, 5 May

Dear Vaccines Working Group,

We are looking forward to our next Vaccines Working Group meeting with you, today (Tuesday) at 12pm ET (9am PT / 6pm CEST). The key agenda items for our meeting are:

- Review new mandates for the Working Group
- Discuss pathways to approval/authorization using correlates and other evidence
- Share ACTIV external communications approach

The slides that we will use during the meeting are attached, with some additional slides drawn from the presentation Marion Gruber shared (attached in full in Friday's notes) in an appendix for reference.

We also want to share an update related to the first agenda item. The Vaccines Clinical Trials Sub-Group met for the first time yesterday (Monday). Much as we anticipate the master protocol trial doing, we rapidly enrolled participants (though perhaps with limited informed consent) in this Sub-Group; the roster as of today is attached, with some additional invitations pending. We have also attached the notes from that meeting.

As always, please do not hesitate to reach out with any input or questions.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T] Sent: Sunday, May 3, 2020 5:45 PM

Subject: Vaccines Working Group important update: Clinical Trial plans

Dear Vaccines Working Group,

Yesterday evening there was an exciting expansion of the opportunity for the Vaccines Working Group to contribute to accelerating vaccine development. We learned that there will be US government funding for a master protocol phase 2/3 adaptive vaccine efficacy trial, with provisions to add and drop vaccine candidate arms over time.

The Clinical Trial Sub-Group (slight name change) will be tasked with supporting this master protocol trial, including the protocol and the networks/sites implementation. The goal is to have this trial ready to start by July 1, though there may be an opportunity to start in June if the work can be completed by then.

This is a significant expansion of scope for the Sub-Group. Given the magnitude of this responsibility, we will be asking for additional representation on the Sub-Group and pulling in expertise, including some of the master protocols experts that have been writing the ACTIV therapeutics protocols. The first meeting of the Sub-Group is tomorrow at 10am ET (7am PT / 4pm CEST).

We will also discuss this at the Vaccines Working Group meeting on Tuesday at 12pm ET (9am PT / 6pm CEST). Please don't hesitate to reach out with any questions.

Best regards,
Mike, for the Vaccines Working Group

Michael Santos, PhD

Associate Vice President, Science

Foundation for the National Institutes of Health

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	Menon [Sandeep.M.Menon@pfizer.com]; Amanda Peppercorn b6 ; Sandeep					
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Subject:	ACTIV TX-Clinical Master Protocol Subgroup #15					
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Start:	5/11/2020 5:00:00 PM					
End:	5/11/2020 6:00:00 PM					
Show Time As:	lentative					

Required

Attendees:
Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo

(FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda

Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne

(FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David

(NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Scott Berry; Angus,

Derek; Meredith Buxton; Patterson, Amy (NIH/NHLBI) [E]

Optional

Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley

(NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Goffeney, Robertta

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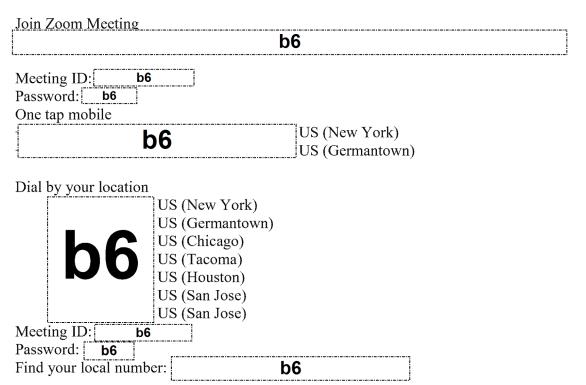
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/7/2020 8:53:35 PM Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) Butterton, Joan ; Collins, Sylva (FDA/CDER) b₆ ; Judy Currier 🏿; De Claro, R. Angelo (FDA/CDER) Keith Gottesdiener]; Mark Eisner b6 b6 b₆]]; Eric Hughes LaVange, Lisa M b6 b6 Elliott Levy ; Sandeep Menon Amanda Peppercorn b6 Proschan, Michael (NIH/NIAID) [E] ; Read, Sarah (NIH/NIAID) [E] 🕆 Amanda Peppercorn]; Price, Dionne (FDA/CDER)]; Rubin, Daniel B. (FDA/CDER) Shen, Yuan Li b6 ; Farley, John (FDA/CDER); -----(FDA/CDER) ; Goff, David b6 Vincent, Michael Wung, Peter /US (NIH/NHLBI) [Ë] b6 Karen Lynn Price Pamela Tenaerts, M.D. Patterson, Amy (NIH/NHLBI) [E] ; Smith, David b6 Kim, Peter (NIH/NIAID) [E] | Eron, b6 b6 h6 b6 Higgs, Elizabeth (NIH/NIAID) [É] Burgess, Timothy b6 Beumont-Mauviel, Maria [JRDUS ; Peeters, Monika [JRDBE] b₆ ; Woodfall, Brian [JRDUS] Van Heeswijk, Rolf [JRDBE] Mellors, John W [-" Mary Biggs ; Demarcus [CC: ገ; Macone, Erin [b6 b6 Tountas, Karen (FNIH) [T] [ktountas@fnih.org]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [tina_butcher@merck.com]; Wholley, David (FNIH) [T] ; Melencio, Cheryl (FNIH) [T] b6 Eron, Joseph J Jr Javan, Arzhang (NIH/NIAID) [E] b6 Subject: ACTIV TX-Clinical Master Protocol Subgroup #15 Attachments: ACTIV Therapeutics-Clinical MP Subgroup 11May2020 Meeting Guide.pdf; Adapt Out COVID Overview051120.pdf Location: Start: 5/11/2020 5:00:00 PM End: 5/11/2020 6:30:00 PM Show Time As: Busy Required Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo Attendees: (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Smith, David; Kim, Peter (NIH/NIAID) [E]; Eron, Joe; Higgs, Elizabeth b6 (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]; Mellors, John W Optional Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Eron, Joseph J Jr; Javan, Arzhang (NIH/NIAID) [E]

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for today's call. We will be discussing the statistical simulations the group has put together for ACTT-3, as well as we will have a presentation from the ACTG group on their outpatient master protocol.

Thanks, Stacey



From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]										
Sent:	5/7/2020 8:56:22 PM										
To:	Eric Hughes b6 Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange										
10.	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa];										
	Ruxandra Draghia-Akli b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative										
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel										
Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group											
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John										
b6 Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group											
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike										
	Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange										
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];										
	Vincent, Michael b6 ; Keith Gottesdiener b6 ; Elliott Levy										
	b6 ; Wung, Peter /US [b6 ; Koroshetz, Walter (NIH/NINDS) [Е]										
	[/o=ExchangeLabs/ou=Exchange Administrative Group										
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth										
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group										
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner										
	b6 ;; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group										
·	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]										
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative										
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa										
	Maria [rosalvarez@deloitte.com]; Salathin, Carla [
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group										
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]										
	[/o=ExchangeLabs/ou=Exchange Administrative Group										
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)										
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group										
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]											
						Subject:	ubject: ACTIV TX-Clinical Agent Prioritization Subgroup #9				
						Location:	on: b6				
Start:	5/12/2020 5:00:00 PM										
End:	5/12/2020 6:00:00 PM										
Show Time As:	Tentative										
Required	Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine										
Attendees:	(NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR);										
	Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs,										
	Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]										
Optional	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; b6										
Attendees:	Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula										
	(NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] b6										
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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]					
Sent:	5/7/2020 8:56:23 PM					
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes					
	b6 Read, Sarah (NIH/NIAID) [E] b6 Ruxandra Draghia-Akli					
	b6 ; Mellors, John W b6 Naimish Patel b6 Colvis,					
	Christine (NIH/NCATS) [E] b6]; Young, John b6]; Stein, Peter					
	(FDA/CDER) b6 ; Poole, Mike b6 ; Buchman, Tim					
	(OS/ASPR/BARDA) (CTR) [b6 ; Vincent, Michael b6 ; Keith					
	Gottesdiener b6 ; Elliott Levy b6 Wung, Peter /US					
	b6 ; Koroshetz, Walter (NIH/NINDS) [E] b6]; Higgs, Elizabeth					
	(NIH/NIAID) [E] b6]; Carlos O Garner b6 ; Goff, David (NIH/NHLBI) [E]					
	b6					
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] b6 Alvarez, Rosa Maria					
	[rosalvarez@deloitte.com]; Salathin, Carla [b6					
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group					
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]					
	[dwholley@fnih.org]; Melencio, Cheryl (FNIH) [T] b6 ; Lucas Smalldon					
	b6 Ward, Jackie b6 Ward, Jackie					
	(NIH/NINDS) [E] b6					
Subject:	ACTIV TX-Clinical Agent Prioritization Subgroup #9					
Location:	b6					
Start:	5/12/2020 5:00:00 PM					
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Required Attendees:	Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]					
Optional	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; b6					
Attendees:	Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula					
	(NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] b6					
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10.	Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Jo					
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		n=Recipients/cn=890082c7		0cd16650-jscurrier	.m]; De Claro, R. Angelo	
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]; Wung, Peter /US	b6	; Karen Lynn	Price	
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	NO	Angus, Derek	b6	; ivieredith Buxto		
	Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group					
		n=Recipients/cn=afad1ca74				
CC:	, 00 (b6 ; Demarcus		, Macone, Er	in b6	
	Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group					
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan					
	[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]					
	[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina					
	(FYDIBOHE23SPDL1)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina b6					
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)					
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Subject:	ACTIV TX-Clinical Maste	er Protocol Subgroup Meet	ing #16			
Location:		b6				
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Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo

Attendees:

(FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda
Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne
(FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David
(NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Scott Berry; Angus,
Derek; Meredith Buxton; Patterson, Amy (NIH/NHLBI) [E]

Optional

Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley

(NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Goffeney, Robertta

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From:	Adam, Stacey (FNIH	,	·				
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To:	Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group						
							ette, Sam (NIH/NCATS)
	[E] b6		utterton, Joan	b6		Collins, Sylva (FD.	
	b6]; Ju	dy Currier	b6	; De	Claro, R. Angelo (FI	DA/CDER)
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	b6		1	ael (NIH/NIAID)) [E]	b6	; Read, Sarah
	(NIH/NIAID) [E]	b6		Peppercorn	NE ANGRES ANGRES SERVICES	b6	Price, Dionne
	(FDA/CDER)	b6	į; Rubin, L	aniel B. (FDÄ/C	\	D6	Shen, Yuan Li Vincent, Michael
	(FDA/CDER)	b6	; Wung, Peter /US	ohn (FDA/CDER b6	<u>L</u>	b6 Karen Lynn Price	•
	b6		Pamela Tenaerts, N		b6	. '	n, Amy (NIH/NHLBI) [E]
	b6		erman, Laura	b6		iggs, Elizabeth (NIH	
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;	b6	<i> </i> ;	Beumont-Mauviel	Maria [JRDUS]			eeters, Monika [JRDBE]
	b6		dfall, Brian [JRDUS]			Van Heeswijk, Roll	f [JRDBE]
	b6		David (NIH/NHLBI)				strative Group
	(FYDIBOHF23SPDLT				4cfbb99		
CC:	Mary Biggs	b6	; Demarcus	b6		j; Macone, Erin	b6
	Tountas, Karen (FN	,				el@deloitte.com]; [
	[elkim@deloitte.co						
	(FYDIBOHF23SPDLT)/cn=Recipi	ents/cn=306b2244 /holley, David (FNIF	466140таа95аа: I) [Т] b			
	b6		Katherine	b6	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Melencio, Cheryl	(FIVITI) [1]
	b6	, i orster, i	Katherine [<u>j</u>		
Subject:	ACTIV TX-Clinical M	laster Proto	col Subgroup Meet	ing #16			
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Location: Start: End: Show Time As: Required	5/13/2020 5:00:00 5/13/2020 6:00:00 Busy Bozzette, Sam (NIH (FDA/CDER); Mark Peppercorn; Prosch	PM PM /NCATS) [E] Eisner; Keith	b6 ; Joan Butterton; C n Gottesdiener; Eric l (NIH/NIAID) [E]; R	ollins, Sylva (FD, Hughes; Lisa La ead, Sarah (NIH,	aVange; E /NIAID) [E	lliott Levy; Sandeer E]; Amanda Pepper	Menon; Amanda corn; Price, Dionne
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Location: Start: End: Show Time As: Required Attendees: Optional Attendees: Stacey Adam Join Zoom M Meeting ID:	5/13/2020 5:00:00 5/13/2020 6:00:00 Busy Bozzette, Sam (NIH (FDA/CDER); Mark I Peppercorn; Prosch (FDA/CDER); Rubin, (NIH/NHLBI) [E]; Vin (NIH/NHLBI) [E]; Est Mauviel, Maria [JRI Mary Biggs; Demark (NIH/OD) [E]; Butch is inviting you to Meeting	PM PM /NCATS) [E] Eisner; Keith nan, Michae , Daniel B. (I ncent, Mich serman, Lau DUS]; Peetel cus; Macon ner, Tina; Wi	; Joan Butterton; C n Gottesdiener; Eric l (NIH/NIAID) [E]; R FDA/CDER); Shen, Y ael; Wung, Peter /L ura; Higgs, Elizabeth rs, Monika [JRDBE]; e, Erin; Tountas, Ka holley, David (FNIH uled Zoom meet	ollins, Sylva (FD, Hughes; Lisa La ead, Sarah (NIH, uan Li (FDA/CDI IS; Karen Lynn F (NIH/NIAID) [E Woodfall, Briar ren (FNIH) [T]; V) [T]; Melencio,	aVange; E /NIAID) [E ER); Farle Price; Pam]; James F n [JRDUS] Vachtel, J	lliott Levy; Sandeer E]; Amanda Peppero y, John (FDA/CDER) nela Tenaerts, M.D. Palazzolo; Burgess, ; Van Heeswijk, Rol onathan; Elizabeth	Menon; Amanda corn; Price, Dionne); Goff, David ; Patterson, Amy Timothy; Beumont- f [JRDBE] Kim; Parker, Ashley

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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	5/7/2020 9:04:21 PM
To:	Eric Hughes b6]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
10.	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa];
	Ruxandra Draghia-Akli b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative
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	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel b6 Colvis,
	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John
	b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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	b6 ; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent Michael
	Throates Throates The Target Control of the
	b6 Wung, Peter /US b6 Koroshetz, Walter (NIH/NINDS) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner
	b6 ; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	Maria [rosalvarez@deloitte.com]; Salathin, Carla b6
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	b6 ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject:	ACTIV TX-Clinical Agent Prioritization Subgroup #10
Location:	b6
Start:	5/14/2020 5:00:00 PM
End:	5/14/2020 6:00:00 PM
Show Time As:	Tentative
Required	Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine
Attendees:	(NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR);
	Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs,
	Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; b6
Attendees:	Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula
	(NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] b6
Stacey Adam	is inviting you to a scheduled Zoom meeting.
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US (San Jose)
US (Tacoma)

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Pind your local number: b6

From:	Adam, Stacey (FNIH) (FYDIBOHF23SPDLT),		•						
Sent:	5/7/2020 9:04:22 PM		13/CN=DCD8/3	100/30466	23E1CL101(JU343414- <i>F</i>	(DAIVISJ4]		
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!	b6		Sarah (NIH/NI		b6		ıxandra Dra	-	
	b6	; Mellors, J			Naimish Pat		b6	; Colvi	s.
į	Christine (NIH/NCAT	!*	b6	; Young, J		b6	······	Stein, Peter	-,
	(FDA/CDER)	b6	; Poole, Mi		b6		Buchn'	nan, Tim	
	(OS/ASPR/BARDA) (C	TR)	b6	, Vincent, N		b	6	; Keith	
	Gottesdiener	b6); Ell	iott Levy!	b6		ung, Peter ,	rus ⁱ	
	[Peter.Wung@sanof	.com]; Korosh	etz, Walter (NI	H/NINDS) [Ē		b6	Hię	ggs, Elizabeth	
	(NIH/NIAID) [E]	b6	Carlos O (arner	b6		; Goff, Davi	id (NIH/NHLBI)	[E]
	b6]							
CC:	Elizabeth Kim [elkime			seph (FNIH)) [T]	b6	; Alvarez	, Rosa Maria	.,
	[rosalvarez@deloitte		· L			b6			}
	Parker, Ashley (NIH/								
	(FYDIBOHF23SPDLT)							ey, David (FNII	H) [T]
	b6	; Melencio, Ch	eryl (FNIH) [T]	•		ucas Small			
	b(Paula (NIH/I	NINDS) [E]	b6	6	; Ward, Jacki	
	(NIH/NINDS) [E] Account [FNIH@rose	b6	Dana Car	uccio[Rose Li Centra	ıl.
	Account [FINITI@1056	massociates.co	mj						
Subject:	ACTIV TX-Clinical Age	ent Prioritizatio	n Subgroup #1	10					
•	IL-6 Trial Information				Prioritizatio	n Sub Grou	n 14May20	120 Meeting	
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Required	Eric Hughes; Read, Sa			_					3
Attendees:	(NIH/NCATS) [E]; You							, , , , , , , , , , , , , , , , , , , ,	
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Attendees:	Parker, Ashley (NIH/O							ral Account	auld

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for tomorrow's call. We will use them to follow up on our conversations from Tuesday, and well as discuss next steps.

The materials include:

- 1. Meeting slides for tomorrow, which have both the updated Agent Prioritization Criteria and Weighted Scoring Rubric for your review. Please take a look and see if Elizabeth and I captured all your thoughts from Tuesday.
- 2. Slides with Status of IL-6 trials for three agents in the clinic. Please take a look at these slides and see if this is the type of snapshot information you have wanted to be able to pull for any given agent as you review. While I know there is some desirable information missing, such as RCT vs. uncontrolled trial, if it looks good, feel free to play around a bit more with the tracker from Oxford that I pulled the data from: http://covid19.trialstracker.net/data_viz.html. What I am hoping to understand is if there are publicly available sites that can help fill our data aggregation needs until we can potentially get access to others that maybe more

- comprehensive. For comparison to the Oxford site, you can check out the Cytel site which maps the trials to given countries, but only shows intended accrual and not current accrual like the Oxford site: https://covid19-trials.com/. The challenge is likely that we may need a couple sites to fulfill the information that we need, but it would prevent us from reinventing the wheel that other maybe creating already. I will continue exploring options, but thanks for reviewing.
- 3. Finally, as discussed on Tuesday, the preclinical group and our team have worked to put together a first version of the company survey/RFI that we would use for multiple purposes: 1) to do specific information solicitation on high priority compounds that this group wishes to score, 2) to have any company or group who has submitted an agent for your consideration populate this so we are working on the right data, and 3) potentially to do a broad company solicitation of additional compounds that the companies would like to have considered for testing.

Please review and let us know if this has all the questions you would want to see to ensure that we will have the right data to review for our high priority compounds. We have worked to balance being thorough with making sure it is not too onerous for a company to fill out. Please let us know if you have any amendments or additions.

Thank you for your review of these materials. We look forward to a productive call tomorrow.

Thanks, Stacey Join Zoom Meeting **b6** Meeting ID: **b6** Password: b6 One tap mobile US (Chicago) **b6** US (New York) Dial by your location US (Chicago) US (New York) US (Germantown) US (Houston) US (San Jose) US (San Jose) US (Tacoma) Meeting ID: b6 Password: **b6** Find your local number: b6

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Attendees:
Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo

(FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda

Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne

(FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David

(NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Scott Berry; Angus,

Derek; Meredith Buxton; Patterson, Amy (NIH/NHLBI) [E]

Optional

Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley

(NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Goffeney, Robertta

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	Tountas, Karen (FNIH) [T] [ktountas@fnih.org]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim
	[elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters,
	Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]
Optional	Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley
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Subject:	ACTIV TX-Clinical Working Group #6
Attachments:	FDA Guidance on COVID Trials.pdf; ACTIV Therapeutics-Clinical Full Working Group_14May2020 Meeting Guide.pdf
Location:	b6
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	Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH)
	[T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs,
	Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E];
	Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]
Optional	Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas
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	Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman,
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	(NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] b6

Dear TX-Clinical Working Group,

Please find attached the slides for tomorrow's call to help facilitate our report outs from both groups. If you have any additions or amendments to propose, please send them to me.

The co-chairs will be updating the group on the ACTIV Executive Committee's feedback and promised actions in response to our letter. This will include some immediate next steps for our group on the mAbs master protocol discussion. Thank you all once again for this feedback to the leadership. It was well received, and it looks like will elicit immediate action on some of the requests.

In addition, please find attached the FDA Guidance for COVID-19 trials that was released today. You can also find it at this link if needed: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-developing-drugs-and-biological-products-treatment-or-prevention

Thanks, Stacey Join Zoom Meeting b6 Meeting ID: b6 Password: **b6** One tap mobile US (Chicago) b6 US (New York) Dial by your location US (Chicago) US (New York) US (Germantown) US (Tacoma) US (Houston) US (San Jose) US (San Jose) Meeting ID: b6 Password: **b6**

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Looking forward to tomorrow's call.

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Subject: Attachments:	ACTIV Clinical Trial Capacity Working Group - reporting meeting ACTIV Partnership Leadership Team Meeting 20200506 FINAL CTC WG slides.pdf; Clinical Trial Capacity Working Group Meeting Agenda_05072020.pdf
Location:	b6
Start: End: Show Time As:	5/8/2020 1:00:00 PM 5/8/2020 2:00:00 PM Tentative
Recurrence:	Weekly
Required Attendees:	every Tuesday and Friday from 9:00 AM to 10:00 AM Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Woodcock, Janet (FDA/CDER); Qashu, Felicia
Optional Attendees:	Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Garner, Carlos; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] 6 Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] 6 homas, Ashley (FDA/CDER); Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich
	nes – Attached is the meeting agenda along with slides that the WG co-chairs, Betsy Desrosiers and Mike nted to the ACTIV Leadership on Wednesday. Best, Karen
ACTIV: Acce	elerating COVID-19 Therapeutic Interventions and Vaccines
Dear Clinical	Trial Capacity Working Group members,
have agreed the areas of need, understand the	n of this working group making rapid progress on identified action items and other activities, the co-chairs nat it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify and to determine next steps. We ask that you make every effort possible to join each of these meetings, but at at times you may have competing priorities. To place a hold on your calendar, please accept this meeting response; later you can decline an individual meeting if you have a conflict.
An agenda an	d other meeting materials, as needed, will be distributed prior to each call.
With best rega Karen	ards,
	ntas, PhD gram Manager or the National Institutes of Health
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CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
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Subject:	RE: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #8

Dear TX-Clinical Agent Prioritization Subgroup,

Please find below the action items from today's meeting. Keith has already been kind enough to follow up on his and let us know that Allergan does not have another study planned at this time.

As for the other Sarah, Eric, Elizabeth, and I will begin working on a strawman for this team's review next week.

Thanks, Stacey

	Action Items	
	Information	POC
1	Learn whether CCR5 cenicriviroc is planned to go into another trial	Keith Gottesdiener
2	Amend/create materials needed for revised scoring process	Sarah Read, Eric Hughes, Stacey Adam, Elizabeth Kim

Stacey J. Adam, PhD

Director, Cancer

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/8/2020 2:20:33 AM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner ; Keith Gottesdiener b6
; LaVange, Lisa M b6
6 ; Amanda Peppercorn ; Eric Hughes Menon b6 ; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn ; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael
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 ; Wung, Peter /US
 b6
 ; Karen Lynn Price

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 } Pamela Tenaerts, M.D.
 b6
 ; Patterson

 [/o=ExchangeLabs/ou=Exchange Administrative Group
 ; Patterson, Amy (NIH/NHLBI) [E] (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa] ; Demarcus **b6** ; Macone, Erin CC: Mary Biggs Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina ; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc] Subject: Material for ACTIV TX-Clinical Therapeutics Master Protocol Subgroup Meeting #14 Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_8May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical MP Sub Group 8May2020 Meeting Agenda.pdf

Dear ACTIV TX-Clinical Therapeutics Master Protocol Subgroup,

Please find attached the agenda and slides for our portion of the meeting tomorrow. As you will note, the first half of the call will be the REMAP-COVID team presenting to our group.

Thanks, Stacey

Stacey J. Adam, PhD Director, Cancer Research Partnerships Direct: **b6** b6 Mobile: Join Zoom Meeting b6 Meeting ID: b6 Password **b6** One tap mobile US (Chicago) **b6** US (New York) Dial by your location US (Chicago) US (New York) US (Germantown) US (Tacoma) US (Houston) US (San Jose) US (San Jose) Meeting ID b6 Password: b6 Find your local number: b6

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/8/2020 2:20:43 AM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner ; Keith Gottesdiener ; Eric Hughes LaVange, Lisa M Sandeep ; Amanda Peppercorn Proschan, Michael Menon b6 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn ; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael ; Karen Lynn Price **b6** ; Scott Berry Pamela Tenaerts, M.D. **b6** ; Scott ; Meredith Buxton Angus, Derek b6 Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa] CC: b6 ; Demarcus b6 ; Macone, Erin Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Goffeney, Robertta b6 Subject: ACTIV TX-Clinical Therapeutics Master Protocol Subgroup #14 Attachments: ACTIV Therapeutics Clinical MP Sub Group 8May2020_Meeting Agenda.pdf Location: **b6** Start: 5/8/2020 5:00:00 PM End: 5/8/2020 6:00:00 PM Show Time As: Tentative

Required Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo Attendees: (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Scott Berry; Angus, Derek; Meredith Buxton; Patterson, Amy (NIH/NHLBI) [E] Optional Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Goffeney, Robertta

Dear ACTIV TX-Clinical Therapeutics Master Protocol Subgroup and Invited Guests,

Please find attached the agenda for our portion of the meeting tomorrow. As you will note, the first half of the call will be the REMAP-COVID team presenting to our group. We are looking forward to hearing more about their efforts.

Thanks, Stacey Join Zoom Meeting b6 Meeting ID: Password: One tap mobile US (Chicago) **b6** US (New York) Dial by your location US (Chicago) US (New York) US (Germantown) US (Tacoma) US (Houston) US (San Jose) US (San Jose) Meeting ID: b6 Password: b6 Find your local number:

b6

From: Read, Sarah (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=527B160038004A199AE6E0BAC2226099-READSA]

Sent: 5/8/2020 3:07:23 PM

To: Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Collins, Francis

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

Subject: RE: ACTIV antivirals

Yes, that is correct Walter. Our plan is to have closer coordination with the ACTIV preclinical group as well as Gates with Mike Poole in our group for future rounds of prioritization to make sure we have the most reliable data available.

Sarah

From: Koroshetz, Walter (NIH/NINDS) [E]		b6
Sent: Friday, May 8, 2020 10:40 AM		
To: Collins, Francis (NIH/OD) [E]	h.C	
Cc: Read, Sarah (NIH/NIAID) [E]	b6	
Subject: ACTIV antivirals		.

Dear Francis

Sarah can correct me, but our ACTIV group was not confident about the potency claims of the different antivirals. For some compounds there were disparate reports, off by factor of 10 or more. I think this is the major reason we did not put an anti-viral forward in the first go around.

We understand that there are at least two standardized assay systems set up to compare 100's of antivirals (I thought Gates foundation in Leuven and another in US). We are hoping that this will give data in that would enable us to choose among the many. Just need to ensure that the ones that come to us can be tested in these standardized assays.

Walter

Walter J. Koroshetz, M.D.

Director, National Institute of Neurological Disorders and Stroke

From: Wachtel, Jonathan [jwachtel@DELOITTE.com] Sent: 5/8/2020 3:11:02 PM To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Vincent, Mike **b6**; Bascles, Lionel **b6** Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King.]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura

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Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm] CC: Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Kenny, Dermot b6 Garner, Carlos b6 Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John j; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Carluccio, Dana b6 Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny b6 James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose b6 ; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy **b6** ... Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative $Group\ (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd];\ Criffield,\ Robin and the control of$

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	[bstratton@DELOITTE.con	n]; Tolman, Brett [btolman@de	loitte.com]; Vict	oria Davey [/o=ExchangeLabs/ou=E	xchange
	Administrative Group (FYI	DIBOHF23SPDLT)/cn=Recipients	/cn=2c8291f38e	c342f895243c0617e115ec-victoria.	.da];
	Jintanat Ananworanich [b6			
Subject:	RE: ACTIV Clinical Trial Cap	pacity Working Group - reportin	g meeting		
Attachments:	Network Inventory Maste	r Spreadsheet 05082020.xlsx			

CTC WG Members-

Please find the most current Network Inventory spreadsheet. If you look at the bottom rows on the tab titled 'Other' you will see both the CROs and SMOs we are currently tracking. Let me know if you have others to add to this list – please include contact info as well.

<u>Laura/Betsy</u> – can you send me the POC/email for the following CROs, even though you will send direct to your contacts. I don't have them in my tracker.

- ICON
- PRA
- SYNEOS
- Parexel

Jonathan Wachtel

THANKS!!

Deloitte Consulting LLP Tel/Direct: +1 301 275 8249 www.deloitte.com ----Original Appointment---From: Tountas, Karen (FNIH) [T] b6 Sent: Tuesday, April 14, 2020 6:40 PM

To: Tountas, Karen (FNIH) [T]; Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James (OS/ASPR/BARDA); Kurilla, Michael (NIH/NCATS) [E]; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manizhe (NIH/NIAID) [E]; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Woodcock, Janet (FDA/CDER); Qashu, Felicia (NIH/OD) [E]

Cc: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Garner, Carlos; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Melencio, Cheryl (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Gonzalez, Nina; Heaton, Penny; James, Stephanie (FNIH) [T]; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Tuvesson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Katz, Rebecca (NIH/NCATS) [E]; Thomas, Ashley (FDA/CDER); Stratton, Benjamin; Tolman, Brett; Victoria Davey; Jintanat Ananworanich

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting

Where:				b	6			<u>-</u>	
When: F	riday, May l	8, 2020 9:0	00 AM-10:00) AM ((UTC-05:00)	Eastern	Time	(US &	Canada).

Dear Colleagues – Attached is the meeting agenda along with slides that the WG co-chairs, Betsy Desrosiers and Mike Kurilla, presented to the ACTIV Leadership on Wednesday. Best, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

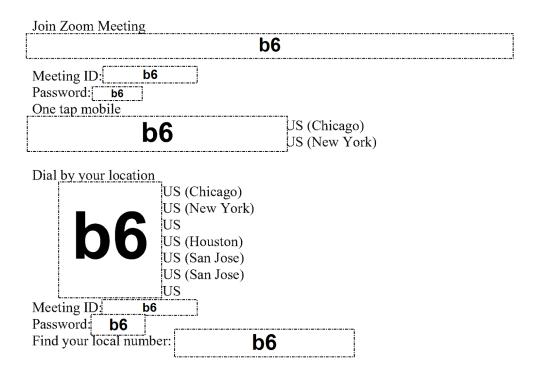
Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards, Karen

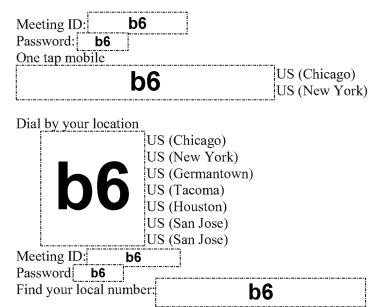
Karen H. Tountas, PhD Scientific Program Manager Foundation for the National Institutes of Health



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	b6			(NIH/NHLBI)	[E] <u> </u>	b6	; Kurilla	a, Michael (NIH/NCATS)	[E]
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	^[E] b6	•	Hill, Zoe (NIF		b6			y (FNIH) [T]	~	
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	Carluccio, Dana		b6			, Nina [nir			m]; Heaton,	, Penny
	b6		James, St	ephanie (FNII	I) [T]	b6	Li, Ros	se		
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	Read, Sarah (NIH)	NIAIDITET			oung, John		- b6			j
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Subject:	ACTIV Clinical Tria	al Capacity	Working Gro	up - reporting	meeting					
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_	147 11									
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	every Tuesday an									
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	[E]; Payton, Manz	ine; Qashu	ı, Felicia; Resi	nansky, Laura	; Sizemore,	, Christine	(NIH/FIC)	[E]; Srinivas	an, Badhri; S	Stein,
	Peter (FDA/CDER)); Vincent,	Mike; Wacht	el, Jonathan						
Optional	Criffield, Robin; H	lamilton, N	ancy; Melend	cio, Cheryl (FN	IH) [T]; Mir	nnich, Bet	h; Mueller	-Reichenste	in, Petra; Q	uadros,
Attendees:	Nora; Rebecca (N			b6			LBI) Hill [C]		; Ada	
	Stacev (FNIH) [T]:	Anderson	. Margaret: A	shlev (NIH/O			b6		uccio, Dana;	
	Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] b6 Carluccio, Dana; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH);									
	Tuvesson, Nancy;	•			-		. , -	•		, .
						1/ (VCA 13)	[L], Hughes	3, 1110, 301130	,	_Ovvy,
	Douglas (NCI); Re	au, saran (MITHMAID) [I	LJ, TOURIS, JON	11					
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	Trial Capacity W								d of May.	we'll
assess the nee	d for further mee	tings at th	e end of the	month. Mar	y thanks f	for your p	participati	on! Karen		
Join Zoom M	eeting									
			b6							



From:	Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]							
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai];							
	b6 Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative							
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine							
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E							
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; b6							
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CC:	Diamond, Michael b6 ; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange							
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc];							
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lowy, Douglas (NIH/NCI)							
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Austin, Christopher							
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy							
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T]							
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T]							
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria							
	[rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel,							
	Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes b6 ; Rose Li							
	Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes b6 ; Rose Li b6 Lagos, Enrique (NIH/NCATS)							
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez	, Robin D			
Attachments: ACTIV PRECLINICAL_Animal Model Inventory_20200507.xlsx; Antiviral expert names.docx; Small ar MD.pptx	nimal models d1			

Dear Preclinical Working Group attendees,

Thank you for an interesting a productive meeting today. It really is a pleasure working with you.

We are working on the minutes, but I wanted to distribute the action items so that you can get started on the items that need your input.

- 1. Joe and Rosa to send the animal model inventory excel file to the Preclinical working group and to the leads of the Vaccine working group to review. Specific request: ensure that the all columns needed for prioritization and analysis are captured. (It is easier to take columns away versus adding them after we begin collecting data)
- 2. The Preclinical WG is asked to provide any concerns about proposed members of the in vitro expert panel to Joe by this evening (Saturday afternoon at the latest). If no objections, then Joe will send a letter of invitation to join the ACTIV expert panel and begin to setup an initial meeting.
- 3. Michael Diamond will draft a 1-2 page preclinical asset review sheet (for expert panel review) before the end of the weekend. Joe will send the draft to the Preclinical WG to provide additions from the animal model working group as well as anyone in the WG. This initial in vitro/ in vivo preclinical asset review sheet will be used as a starting point for the expert panels to modify. We will use this to begin setting up an input form for the needed data by potential sponsors.
- 4. Industry members of the working group will suggest people with CRO or industry experience but currently non-conflicted positions to the in vivo expert panel. These will be added to the NIH and academic suggestions by Dr Jim Anderson.
- 5. Jim Anderson and Chris Austin will work to obtain a view into all the NIH data in the publication portal supported by the office of portfolio management.
- 6. Joe will share the slide from Mike Diamond on the cross subgroup information.

Best regards,

Joe and Rosa

----Original Appointment---
From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:48 PM

To b6 ; Menetski, Joseph (FNIH) [T];

b6 | Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]

Cc: Diamond, Michael; Florence, Clint (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Lowy,

[E]; Desrosiers, Betsy; Hughes, Eric; Janse (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Carluccio; Lagos, Enrique (NIH/NCATS) [E (NIH/OD) [E]; Rodriguez, Robin D; Dave F Subject: ACTIV Preclinical working group	· · · · · · · · · · · · · · · · · · ·
Where:	b6
Holding time	
Joseph Menetski is inviting you to a sche	duled Zoom meeting.
Join Zoom Meeting	
b	6
Meeting ID: b6 Password: b6 One tap mobile b6	US (New York) US (Chicago)
Dial by your location US (New York) US (Chicago) US US US (Houston) US (San Jose) US (San Jose) US (San Jose) US (San Jose)	
Find your local number:	b6

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]

Sent: 5/9/2020 1:17:56 AM

To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd] Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Parker, Ashley (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Tabak, Lawrence (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]

Subject: RE: do we need an Executive Committee meeting with the co-chairs sooner rather than later? **Attachments**: ACTIV Executive Committee; ACTIV Executive Committee (ADMINS); ACTIV Working Group Co-chairs

Dear Dr. Collins:

CC:

Attached are the distribution lists for the Executive Committee and the Co-chairs. I have also listed them below.

Executive Committee:

C-II:	N (F3 !	he ::	A + / A + / A A / C	! he	
Collins, Francis (NIH/O))[E] 4	b6 Fauci, <i>i</i>	Anthony (NIH/NIAID) [E]	₹ <u>.</u>	؛; Globons,
Gary (NIH/NHLBI) [E] ﴿	b6	; Stoffels, Pa	aul <u>b6</u>	الحَدِيَّة; Wood, Gretchen (N	IIH/OD) [E]
_b6	Pao, William	b6	; Dolsten, Mikael ﴿	b6	
Co-chairs	·		·;		
Colvis, Christine (NIH/N	ICATS) [E] {	b6	; Desrosiers, Betsy	b6	;
Hughes, Eric			b6	; Kurilla, Michael	(NIH/NCATS)
[E] b6	Lowy, D	ouglas (NCI)	b6 ; Read, Sarah	(NIH/NIAID) [E]	
h6	Young John	he	i		

Let me know if you need anything else.

Cheryl

Cheryl Melencio

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

b6

fnih.org

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From: Collins, Francis (NIH/OD) [E] b6
Sent: Friday, May 8, 2020 7:32 PM
To: Wholley, David (FNIH) [T] b6
Cc: Melencio, Cheryl (FNIH) [T] b6 ; Wood, Gretchen (NIH/OD) [E] b6 ; Parker, Ashley (NIH/OD) [E] b6 Tabak, Lawrence (NIH/OD) [E] b6
Subject: RE: do we need an Executive Committee meeting with the co-chairs sooner rather than later?
Thanks for drafting this. I've made a few edits. Can Cheryl send me the e-mail list for the co-chairs and the Exec Comm?
I don't think I have seen the letter from the Clinical Therapeutics WG. Is there some chance this invitation to convene with the Exec Comm, sent very soon, will encourage them to hold their fire – at least for a while?
FC
From: Wholley, David (FNIH) [T] b6
Sent: Friday, May 8, 2020 7:03 PM
To: Collins, Francis (NIH/OD) [E] b6
CC. Meletico, Cheryr (FMin) [1] S. C. Me
Subject: RE: do we need an Executive Committee meeting with the co-chairs sooner rather than later?
Dear ACTIV Executive Committee Members and Working Group Co-Chairs:
Although our first formal ACTIV EC meeting is not scheduled until May 20, I am aware of some concerns that are being
voiced among our Working Group members. Those focus on the next steps for ACTIV, and especially about
implementation of the plans these groups have been working so hard to put together. There are also concerns about
how we should best communicate across our partnership and coordinate with the many parallel (and in some cases
conflicting) efforts that have emerged elsewhere—including among our own ACTIV members.
These are all very valid issues, and I believe they should be discussed by our dedicated team sooner rather than later. A
meeting of the minds is particularly timely now, in the wake of a successful Leadership Team call on Wednesday and the establishment just this week of an Executive Committee to guide us moving forward. Therefore, I would like to make it
priority that the EC and the Working Group co-Chairs meet early next week to discuss and sync up on these important
issues. Gretchen Wood on my staff will work with Cheryl Melencio at FNIH to reach out to you to get a suitable
hourlong set up—a morning meeting would make it easier to include Tony Fauci (because of White House duties in the
afternoon) and Paul Stoffels (because of European time zones).
Thanks for all you are doing for the cause, and best regards,
Francis
From: Collins, Francis (NIH/OD) [E] 4 b6
Sent: Friday, May 8, 2020 6:27 PM
To: Wholley, David (FNIH) [T] Co: Melancia Chard (FNIH) [T] Co: Melancia Chard (FNIH) [T] Co: Melancia Chard (FNIH) [T]
Cc: Melencio, Cheryl (FNIH) [T] ; Wood, Gretchen (NIH/OD) [E] b6 Subject: Re: do we need an Executive Committee meeting with the co-chairs sooner rather than later?
The state of the s

That would be great, you read my mind.

Sent from my iPhone

On May 8, 2020, at 5:55 PM, Wholley, I	David (FNIH) [⊤] {	b6	wrote:
Yes, by all means. I guess I should write	e a brief inv	itation note	to come fr	om you?
From: Collins, Francis (NIH/OD) [E] Sent: Friday, May 8, 2020 5:04 PM To: Wholley, David (FNIH) [T] Subject: RE: do we need an Executive C	b6		the co-ch	airs sooner rather than later?
Totally agree. Could we aim for a m have a better chance to include Ton Cheryl work on this with Gretchen?	_	-		
FC				
From: Wholley, David (FNIH) [T] Sent: Friday, May 8, 2020 4:26 PM To: Collins, Francis (NIH/OD) [E]	b6			
Subject: do we need an Executive Com	mittee mee	ting with the	co-chairs	sooner rather than later?

Francis,

In talking with my team today, the same issues that the TX-Clinical group is writing about came up on the Clinical Trial Capacity call: we need better coordination of ACTIV with other external efforts that appear duplicative, we need better communications across groups, and above all it is time for us to make decisions about ACTIV implementation and to do that we need to understand how that will be funded and managed and where this is all going. This is coming from co-chairs and rank and file members of these Working Groups, from NIH and FDA and industry members, some of whom are fairly highly placed.

It seems to me we need a forum for a frank dialogue between the EC and the co-chairs to discuss and communicate on these issues. The Leadership Team calls are not the forum for this, and it should not be coming from me. I am worried that this chorus is going to continue to get louder if we don't speak sooner than our next scheduled EC, which would be May 20. I recommend we seek to set something up before then, focused on exactly these issues rather than the usual show and tell.

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
Cant:	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: To:	Eric Hughes (
CC:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc] Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	Maria [rosalvarez@deloitte.com]; Salathin, Carla b6
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	Malker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Attachments:	Follow-up from ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #8 2020-05-07_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting Summary.pdf
Dear TX-Clinio	cal Agent Prioritization Subgroup,
=	for a very productive discussion on the re-evaluation of the criteria and how we will approach our next tization. Elizabeth and I are working on some materials for your review at our meetings next week.
For now, plea additions or a	se find the formal summary of the meeting attached for your review. Please let me know if you have mendments.
Thanks, Stacey	
Stacey J. Ad	am, PhD
Director, Can	
Research Part	nerships or the National Institutes of Health
Direct:	b6 Mobile: b6
fnih.org	

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/9/2020 2:47:21 AM Sent: To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra b6 ; Eisner, Mark b6 ; Gottesdiener, Keith b6 ; Hughes, Eric b6 ; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa b6]; Levy, Elliot b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep b6 ; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish b6 Peppercorn, Amanda b6 ; Poole, Mike b6 Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn Garner, Carl **b6**; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy b6 ; Jansen, Kathrin b6 ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Anderson, Margaret [marganderson@deloitte.com]; Lucas

Smalldon **b6** Stratton, Benjamin [bstratton@DELOITTE.com]; Qashu, Felicia

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-gashufm]

Subject: Follow-up from the ACTIV TX-Clinical Working Group #5 **Attachments**: 2020-05-07_TX-Clinical_WG_Meeting_Summary.pdf

Dear TX-Clinical Working Group,

Please find attached the formal summary from yesterday's WG meeting. I want to thank you all for your candid feedback and earnest desire to see this process succeed. All your time and efforts are truly greatly appreciated!

Some of you have reached out to ask, so I will note, that no, you have not missed the letter that the team is drafting to the ACTIV Executive Committee. The group is just working to ensure the best possible case is made for the group's request. We hope to share the note with you all soon for review.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

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Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] 5/9/2020 7:52:47 PM Sent: b6 Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group To: Bascles, Lionel (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry ; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy b6 ; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos ighthalphalia [Value of the content (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura ; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri **b6** ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group <u>(FYDIBOHF23SPDLT)/cn=Recipi</u>ents/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike ; Wachtel, Jonathan [jwachtel@deloitte.com] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric b6 ; Lowy, Douglas (NCI) ; Jansen, Kathrin [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Heaton, Penny **b6** ; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange ; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Heaton, Penny Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, ; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy ;; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth ; Mueller-Reichenstein, Petra <u>b6</u>; Quadros, Nora ; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs] Subject: Summary and action items - CT Capacity WG meeting #7

Attachments: Clinical_Trial_Capacity_Working_Group_Meeting 7_Summary_Final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #7 (May 8, 2020) of the full working group. The next full working group meeting is scheduled for Friday, May 8 at 9 am eastern time USA.

Best regards,

Karen

Karen H. Tountas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

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Required Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo Attendees: (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Smith, David; Kim, Peter (NIH/NIAID) [E]; b6 ; Eron, Joe; Higgs, Elizabeth (NIH/NIAID) [E] Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley Optional Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Eron, Joseph J Jr Stacey Adam is inviting you to a scheduled Zoom meeting. Join Zoom Meeting **b6** b6 Meeting ID: Password: One tap mobile US (New York) **b6** US (Germantown) Dial by your location US (New York) US (Germantown) US (Chicago) US (Tacoma) US (Houston) US (San Jose) US (San Jose) Meeting ID b6 Password: b6

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Corey MD, Larry Sent: 5/11/2020 1:35:18 AM Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf] Subject: slides from today and ACTIV Vaccine Committee Attachments: harmonized versus compartaive trials_.pptx Flag: Follow up Francis, here are this morning's slides. As John articulated on the phone he and I have had frequent communication with Doug ; debriefing each week for an hour just the three of us . Last Thursday, we have outlined the strategy for the recently composed Clinical Development subcommittee of the Vaccine Committee . I lead this subcommittee with Paula Annunziato from Merck . Paula and I had an hour talk Saturday night (yes a zoom date) to go through the agenda for this Wednesday 's upcoming call . We will be sending everyone the Science article we wrote coming out Monday as background. We will then outline the goals of the clinical development and then move to discussing key harmonized elements; let them all interact . on key issues mainly the endpoints , populations , and we will raise the issue of the common DSMB and their ability to send suggestions to Doug and you .. We expanded the subcommittee so that all the Pharma companies on the BARDA list are represented so they will be a part of the process. Paula is a big fan of the harmonized design; she voices the issue all Pharma companies have in a real viable market; they don't want head to head comparisons; parallel universes is how they always operate. The global strategy and the link to WHO are my next on the plate issues perhaps worth a chat. If there are other issues of concern just call My cell is Thanks

b6

From:

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/11/2020 2:20:00 AM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra b6 ; Eisner, Mark b6 b6 ; Hughes, Eric b6 Gottesdiener, Keith ; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; LaVange, Lisa Levy, Elliot **b6**]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep Patel, Naimish 6 Peppercorn, Amanda
Poole, Mike 66 Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn Garner, Carl 66 Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy **b6** Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa] CC: Kim, Elizabeth [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-gashufm] Subject: Updates from Last Wednesday's ACTIV Leadership Meeting Attachments: ACTIV Partnership Leadership Team Meeting 20200506 FINAL2.pdf; 2020-05-

Dear ACTIV Therapeutics-Clinical Working Group,

06_ACTIV_Leadership_Group_Meeting_Summary FINAL.pdf

I wanted to share with you some summary materials for the current standing of all 4 working groups within ACTIV. In the hope of providing more clarity into the overarching connectivity of the working group and the directions of the partnership.

Last Wednesday, the ACTIV Leadership Team (the parent body above the Working Groups) met. Sarah and Eric presented the progress and plans of our Working Group and answered questions. The meeting presentation and notes are attached which include similar summaries from all the Working Groups.

If you have specific questions, let us know and we can follow up.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: **b6** Mobile: **b6**

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From:	Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]							
Sent:	5/11/2020 2:35:43 AM							
To:	Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]							
CC:	Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]							
Subject:	FW: slides from today and ACTIV Vaccine Committee							
Need to partic Sorry Larry	icipate in this tomorrow 11;15-11;45, so Julie will need to be rescheduled.							
From: Franci	is Collins b6 by, May 10, 2020 at 10:32 PM							
	Lawrence (NIH/OD) [E]" b6 "Santos, Michael (FNIH) [T]"							
be	hand (Itti) [1]							
Subject: RE:	slides from today and ACTIV Vaccine Committee							
That would b	be great.							
	Lawrence (NIH/OD) [E] b6							
Sent: Sunday,	, May 10, 2020 10:32 PM							
To: Collins, Fr	rancis (NIH/OD) [E] b6 Santos, Michael (FNIH) [T] b6 >; Wholley, Dav	id						
(FNIH) [T]	b6 ; Lane, Cliff (NIH/NIAID) [E] 6							
Subject: Re: s	slides from today and ACTIV Vaccine Committee							
I can join if yo	ou would like me to.							
From: Franci	is Collins b6							
	ny, May 10, 2020 at 10:25 PM							
	Michael (FNIH) [T]" b6 "Tabak, Lawrence (NIH/OD) [E]"							
	"MAN Clay David (FAHL) [T]" LG "II and Cliff (AHL) (AHAID) [F]"							
į k	of , wholley, david (FNIH) [1]							
Subject: RE:	slides from today and ACTIV Vaccine Committee							
I can probab	bly make that work. Please send information about how to link in.							
From: Santos,	s, Michael (FNIH) [T] b6							
Cante Cun day	. May 10, 2020 10:00 DM							
To: Collins, Fr	rancis (NIH/OD) [E] b6 ; Tabak, Lawrence (NIH/OD) [E] b6							
Wholley, Davi	rancis (NIH/OD) [E] b6 ; Tabak, Lawrence (NIH/OD) [E] b6 rid (FNIH) [T b6 Lane, Cliff (NIH/NIAID) [E] b6 slides from today and ACTIV Vaccine Committee							
Junjues III. 3	and the first today and he fire vaccine committee							
Hi Francis,								

LTAB0000019201

have a regularly scheduled call with Kathrin and Doug at 11:15-11:45am tomorrow (Monday) morning. If you can be free then and would like to join, that's an option. If that doesn't work, we can find another time before the Wednesday meeting (1pm).						
Thanks, Mike						
Michael Santos, PhD Associate Vice President, Science Foundation for the National Institutes of Health						
From: Tabak, Lawrence (NIH/OD) [E] 66 Sent: Sunday, May 10, 2020 10:00 PM						
To: Collins, Francis (NIH/OD) [E] b6 ; Wholley, David (FNIH) [T] (FNIH) [T] 6 b6 ; Lane, Cliff (NIH/NIAID) [E] b6 Subject: Re: slides from today and ACTIV Vaccine Committee	b6	; Santos, Michael				
Francis Despite the reassurance on the call today that the issues have been socialized with the have a separate discussion with them. We should do everything possible to make thi Larry	· ·					
From: Francis Collins b6 Date: Sunday, May 10, 2020 at 9:52 PM To: "Wholley, David (FNIH) [T]" b6 ; "Santos, Michael (FNIH) "Tabak, Lawrence (NIH/OD) [E]" b6 ; "Lane, Cliff (NIH,) [T]" [/NIAID) [E]"	b6 ,				
b6 Subject: FW: slides from today and ACTIV Vaccine Committee	,,,,					
See slides and note from Larry Corey.						
Do we need a separate discussion with the Vaccines WG before their Wednes	day meeting?	,				

FC

From: Corey MD, Larry b6

Sent: Sunday, May 10, 2020 9:35 PM

To: Collins, Francis (NIH/OD) [E] b6

Subject: slides from today and ACTIV Vaccine Committee

Francis , here are this morning's slides . As John articulated on the phone he and I have had frequent communication with Doug ; debriefing each week for an hour just the three of us . Last Thursday, we have outlined the strategy for the recently composed Clinical Development subcommittee of the Vaccine Committee . I lead this subcommittee with Paula Annunziato from Merck . Paula and I had an hour talk Saturday night (yes a zoom date) to go through the agenda for this Wednesday 's upcoming call . We will be sending everyone the Science article we wrote coming out Monday as background. We will then outline the goals of the clinical development and then move to discussing key harmonized elements; let them all interact . on key issues mainly the endpoints , populations , and we will raise the issue of the common DSMB and their ability to send suggestions to Doug and you .. We expanded the subcommittee so that all the Pharma companies on the BARDA list are represented so they will be a part of the process . Paula is a big fan of

the harmonized design; she voices the issue all Pharma companies have in a real viable market; they don't want head
to head comparisons ; parallel universes is how they always operate .
The global strategy and the link to WHO are my next on the plate issues perhaps worth a chat.
If there are other issues of concern just call My cell is b6 .
Thanks Larry

Subject:	•	• • • • • • • • • • • • • • • • • • • •	pients/cn=ab38cb683 FIV Vaccine Committe	86de44e18ef4cc6952f65f ee	80-santosmr]	
thanks						
From: "Sant	os, Michae	:I (FNIH) [T]"	b6			
Date: Sunda	ay, May 10,	2020 at 10:35	PIM			
lo: "Tabak,	Lawrence	(NIH/OD) [E]"	b6	, Francis Col e, Cliff (NIH/NIAID) [FI" b	6
Wholley, D	avid (FNIH) []	, "Lan	e, Cliff (NIH/NIAID) [E]" {	
subject: RE:	: slides tror	n today and AC	TIV Vaccine Comn	nittee		
Γhanks, Fran	cis and Larr	y. I have added y	ou to the invite, w	hich you should have j	ust received.	
will let Kath	rin and Dou	g know that you	'll be joining to disc	uss this topic.		
Thanks,						
Vike						
Michael Sant Associate Vice		cience Foundatio	n for the National Ins	titutes of Health		
rom: Tabak	Lawrence (NIH/OD) [F]	b6			
Sent: Sunday	, Lawrence (, Mav 10, 2	020 10:35 PM				
Γο: Collins, Fι	rancis (NIH/	OD) [E]	b6 ; Sant	os, Michael (FNIH) [T]	b6	; Wholley, David
FNIH) [T]	b6	Lane, Cl	iff (NIH/NIAID) [E]	b6		
Subject: Re: s	slides from	today and ACTIV	Vaccine Committe	e		
	lease send r	ne log-in informa	ation as well.			
Thanks						
Larry						
Crama Erana	sis Callins	b6				
		, 2020 at 10:32				
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IO. Tabak,		Wholley David	1 (ENIH) [T]" ;	"Santos, M b6 "La	ane Cliff (NIH/NI	ι ΙΔΙΟ) [Ε]"
b	6	willoney, David	, (, , , , , , , , , , , , , , , , , ,	DO Lo	ine, em (Min, M	
Subject: RF	· slides fror	: n today and AC	TIV Vaccine Comn	nittee		
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That would	be great.					
rom: Tabak,	, Lawrence (NIH/OD) [E]	b6			
		020 10:32 PM		8 4 1 1 / mail 1 / mail	L 0	
Fo: Collins, Fi	rancis (NIH/	OD) [E] (b6 ; Sant	os, Michael (FNIH) [T]	b 6	; Wholley, David
			iff (NIH/NIAID) [E]			
oubject: Re: 9	slides from	today and ACTIV	Vaccine Committee	2		

Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]

Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

From:

Sent:

To:

5/11/2020 2:38:04 AM

I can join if you would like me to. From: Francis Collins Date: Sunday, May 10, 2020 at 10:25 PM To: "Santos, Michael (FNIH) [T]" "Tabak, Lawrence (NIH/OD) [E]" "Lane, Cliff (NIH/NIAID) [E]" "Wholley, David (FNIH) [T] Subject: RE: slides from today and ACTIV Vaccine Committee I can probably make that work. Please send information about how to link in. From: Santos, Michael (FNIH) [T] b6 Sent: Sunday, May 10, 2020 10:09 PM To: Collins, Francis (NIH/OD) [E] Tabak, Lawrence (NIH/OD) [E] b6 Wholley, David (FNIH) [T] ; Lane, Cliff (NIH/NIAID) [E] b6 b6 Subject: RE: slides from today and ACTIV Vaccine Committee Hi Francis, I have a regularly scheduled call with Kathrin and Doug at 11:15-11:45am tomorrow (Monday) morning. If you can be free then and would like to join, that's an option. If that doesn't work, we can find another time before the Wednesday meeting (1pm). Thanks, Mike Michael Santos, PhD Associate Vice President, Science | Foundation for the National Institutes of Health From: Tabak, Lawrence (NIH/OD) [E] **Sent:** Sunday, May 10, 2020 10:00 PM To: Collins, Francis (NIH/OD) [E] b6 Wholley, David (FNIH) [T] b6 Santos, Michael b6 Lane, Cliff (NIH/NIAID) [E] Subject: Re: slides from today and ACTIV Vaccine Committee Francis Despite the reassurance on the call today that the issues have been socialized with the WG, I recommend that we do have a separate discussion with them. We should do everything possible to make this transition as smoothly as possible. Larry From: Francis Collins Date: Sunday, May 10, 2020 at 9:52 PM "Santos, Michael (FNIH) [T]" To: "Wholley, David (FNIH) [T]" **b6** "Tabak, Lawrence (NIH/OD) [E]" b6 ີ່ "Lane, Cliff (NIH/NIAIDັງ ໄຂ້ງ" b6 Subject: FW: slides from today and ACTIV Vaccine Committee

See slides and note from Larry Corey.

Do we need a separate discussion with the Vaccines WG before their Wednesday meeting?

FC

From: Corey MD, Larry	D6	
Sent: Sunday, May 10, 2020 9:35	PM	
To: Collins, Francis (NIH/OD) [E]	b6	
Subject: slides from today and A	CTIV Vaccine Cor	nmittee
,		ohn articulated on the phone he and I have had frequent
	-	eek for an hour just the three of us . Last Thursday, we have
outlined the strategy for the r	ecently compose	ed Clinical Development subcommittee of the Vaccine Committee
. I lead this subcommittee with	h Paula Annunzi	ato from Merck . Paula and I had an hour talk Saturday night (
yes a zoom date) to go throu	gh the agenda f	or this Wednesday 's upcoming call . We will be sending
everyone the Science article we	e wrote coming c	out Monday as background. We will then outline the
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all interact . on key issues ma	ainly the endpoin	nts , populations , and we will raise the issue of the common
DSMB and their ability to send	suggestions to	Doug and you We expanded the subcommittee so that all the
Pharma companies on the BARD	A list are repre	esented so they will be a part of the process. Paula is a big fan of
the harmonized design; she voice	es the issue all	Pharma companies have in a real viable market; they don't want head
to head comparisons; parallel u	niverses is how	they always operate .

From:	Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIV (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D6773		ol .
Sent:	5/11/2020 11:42:13 AM		•
То:	Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Grou	ab	
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-s	antosmr]; Colli	ns, Francis (NIH/OD)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group		
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-c	ollinsf]; Tabak,	Lawrence (NIH/OD)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group		
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-t	abakl]; Lane, C	liff (NIH/NIAID) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group	alama)	
Subject:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de- RE: slides from today and ACTIV Vaccine Committee	-cianej	
oubject.	RE. Silves from today and ACTIV vaccine Committee		
Flag:	Follow up		
l absolutel	y think we need to talk to the WG and share the nuances of the conversation	n.	
From: Sant	tos, Michael (FNIH) [T] b6		
Sent: Sund	lay, May 10, 2020 10:09 PM		
To: Collins	, Francis (NIH/OD) [E] b6 ; Tabak, Lawrence (NIH/OD) [E]	b	6
Wholley, D	lay, May 10, 2020 10:09 PM , Francis (NIH/OD) [E] b6 ; Tabak, Lawrence (NIH/OD) [E] Pavid (FNIH) [T] b6 ; Lane, Cliff (NIH/NIAID) [E] <clane@nia< td=""><td>id.nih.gov></td><td>j</td></clane@nia<>	id.nih.gov>	j
Subject: RI	E: slides from today and ACTIV Vaccine Committee	J	
Hi Francis,			
	gularly scheduled call with Kathrin and Doug at 11:15-11:45am tomorrow (N		
free then a	and would like to join, that's an option. If that doesn't work, we can find and	other time be	ore the Wednesday
meeting (1	.pm).		
Thanks,			
Mike			
Michael Sa	· · · · · · · · · · · · · · · · · · ·		
Associate V	ice President, Science Foundation for the National Institutes of Health		
	-		
	ak, Lawrence (NIH/OD) [E] b6		
	lay, May 10, 2020 10:00 PM	h.c	Carta Natala al
	, Francis (NIH/OD) [E] b6 ; Wholley, David (FNIH) [T]	b6	; Santos, Michael
(FNIH) [T]	i		
Subject: Re	e: slides from today and ACTIV Vaccine Committee		
Francis	and the second s	14/6	
	e reassurance on the call today that the issues have been socialized with the		
	arate discussion with them. We should do everything possible to make this t	ransition as s	moothly as possible.
Larry			
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From: Fra	ncis Collins b6		
Date: Sun	day, May 10, 2020 at 9:52 PM		
To: "Who	lley, David (FNIH) [T]" b6 "Santos, Michael (FNIH) [T]" {	b6
"Tabak La	awrence (NIH/OD) [E]" b6 , "Lane, Cliff (NIH/N	IAID) [E]"	
100011, -			

b6
Subject: FW: slides from today and ACTIV Vaccine Committee
See slides and note from Larry Corey.
Do we need a separate discussion with the Vaccines WG before their Wednesday meeting?
FC
From: Corey MD, Larry b6 Sent: Sunday, May 10, 2020 9:35 PM To: Collins, Francis (NIH/OD) [E] b6 Subject: slides from today and ACTIV Vaccine Committee
Francis , here are this morning's slides . As John articulated on the phone he and I have had frequent communication with Doug ; debriefing each week for an hour just the three of us . Last Thursday, we have outlined the strategy for the recently composed Clinical Development subcommittee of the Vaccine Committee . I lead this subcommittee with Paula Annunziato from Merck . Paula and I had an hour talk Saturday night (yes a zoom date) to go through the agenda for this Wednesday 's upcoming call . We will be sending everyone the Science article we wrote coming out Monday as background. We will then outline the goals of the clinical development and then move to discussing key harmonized elements; let them all interact . on key issues mainly the endpoints , populations , and we will raise the issue of the common DSMB and their ability to send suggestions to Doug and you We expanded the subcommittee so that all the Pharma companies on the BARDA list are represented so they will be a part of the process . Paula is a big fan of the harmonized design; she voices the issue all Pharma companies have in a real viable market; they don't want head to head comparisons; parallel universes is how they always operate .

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]

Sent: 5/11/2020 1:58:43 PM

To: Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]

Subject: FW: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

From: "Wood, Gretchen	` ' ' ' ' ' '				
Date: Monday, May 11, 2	2020 at 9:23 Aľ	M			
To: Francis Collins {	b6	Anthony Fa	uci { b	6 , "Gik	bons, Gary (NIH/NHLBI)
[E]" b6	"Stoffels,	Paul"	b6	, "Pao, William"	
b6	"Dolsten, N	1ikael"	b6	, "Colvis,	Christine (NIH/NCATS)
[E]" b6	, "Desro	siers, Betsy"[b6	, "Hughes, Eric"
b6	"Jansen,	Kathrin"	b6	"Kurill:	a, Michael (NIH/NCATS)
[E]" b6	"Lowy,	Douglas (NCI)	' b6	, "Read, Sarah	n (NIH/NIAID) [E]"
b6	"Young, John"		b6		
Cc: "Wholley, David (FNII					
"Adam, Stacey (FNIH) [T]					
Michael (FNIH) [T]"	b6	, "Freire, Ma	ria (FNIH) [T]"	b6	, "Tabak, Lawrence
(NIH/OD) [E]" <		, "Lane, Cliff	(NIH/NIAID) [E]"[b6	"Parker, Ashley
(NIH/OD) [E]"	DO	'Anderson, J	ames (NIH/OD)	[E]"	b6
"Austin, Christopher (NIF	I/NCATS) [E]'	b6	, "Mel	encio, Cheryl (FN	IIH) [T]"
b6					
Subject: Re: Time sensiti	ve ACTIV mtg	g with Exec Co	mm and WG co	-chairs	

Good morning,

Please mark your calendars for Wednesday, May 13, from 8:00 AM-9:00 AM ET for this call. A calendar invitation will be shared with you soon.

With very best wishes,

Gretchen

From: Francis Collins		b6						
Date: Saturday, May 9	, 2020 at	1:07 PM						
To: Francis Collins	b6		Anthony	Fauci	b6		, "Gibbons, Ga	ry (NIH/NHLBI)
[E]" <u>b6</u>			b6	4	b6	, G	retchen Wood	
√ b6	"Pao, V	Villiam"			b6			
b6		"Colvis, Č	hristine (N	IH/NCATS)	[E]"[b(3	Desrosiers,
Betsy"	b6		, "Hugh	es, Eric"		b6	, "Jans	sen, Kathrin"
b6		'Kurilla, N	∕Iichael (NII	H/NCATS)	[E]'[b6] "	Lowy, Douglas
(NCI)" 66	"Read	, Sarah (N	NIH/NIAID)	[E]"[b6	,	"Young, John"	
b6						,		
Cc: David Wholley	b6		, "Menetsk	i, Joseph (FNIH) [T]" ·	<u></u>	b6 ,	"Adam, Stacey

(FNIH) [T]"	b6⊳, "Tountas, Karen (FN	IIH) [T]"	b6	, "Santos, Michael (FI	VIH) [T]"
b6	Maria Freire b6	"Tabak,	Lawrence (ſ	NIH/OD) [E]"	
b6	>, "Lane, Cliff (NIH/NIAID James Anderson) [E]" {		Austin, Christopher (NIH/N	ICATS)
b6	"Melencio, Cheryl (FN			, , , ,	, , , , ,
Subject: Time sens	itive ACTIV mtg with Exec Com	m and WG c	o-chairs		

Dear ACTIV Executive Committee Members and Working Group Co-Chairs:

Although our next formal ACTIV EC meeting is not scheduled until May 20, I am aware of some concerns that are being voiced among our Working Group members. Some of those focus on the next steps for ACTIV, and especially about implementation of the plans these groups have been working so hard to put together.

b5

These are all very valid issues, and I believe they should be discussed by our dedicated team sooner rather than later. A meeting of the minds is particularly timely now, in the wake of a successful Leadership Team call on Wednesday and the establishment just this week of an Executive Committee to guide us moving forward. Therefore, I would like to make it a priority that the EC and the Working Group co-Chairs meet early next week to discuss and sync up on these important issues. Gretchen Wood on my staff will work with Cheryl Melencio at FNIH to reach out to you to get a suitable hourlong virtual conference set up—a morning meeting would make it easier to include Tony Fauci (because of White House duties in the afternoon) and Paul Stoffels (because of European time zones).

Thanks for all you are doing for the cause, and best regards,

Francis

From:	Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
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Subject: ACTIV mtg with Exec Comm and WG co-chairs
Location: b6

Start: 5/13/2020 12:00:00 PM End: 5/13/2020 1:00:00 PM

Show Time As: Tentative

Required Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Pao, Attendees: William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes,

William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Wholley, David; Menetski, Joseph; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Freire, Maria (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E];

Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]

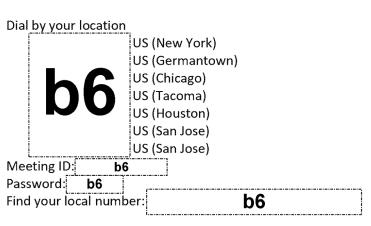
Optional Attendees:

Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Zanellato, Ann; Zottoli, Jessica; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, Dorina (FNIH) [T]; Lagos, Enrique (NIH/NCATS) [E]; Simon,

Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]

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Subject: ACTIV mtg with Exec Comm and WG co-chairs Location: b6

Start: 5/13/2020 12:00:00 PM **End**: 5/13/2020 1:00:00 PM

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Required Attendees:

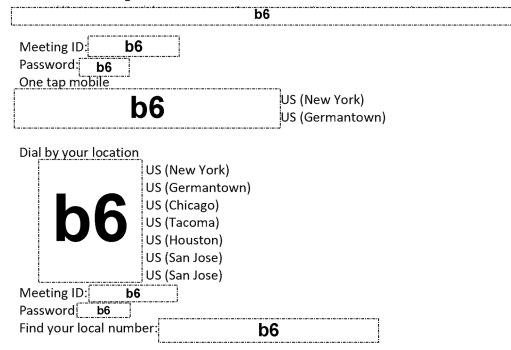
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Optional Attendees:

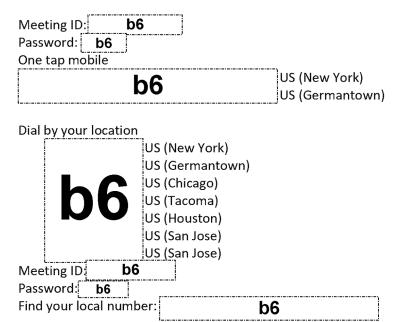
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Sent:	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC] 5/11/2020 2:08:35 PM						
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	b6			b6		Gary (NIH/NHLBI) [E]	
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	Janet (FDA/CDER)	b6	Colvis, Christ	ine (NIH/NCATS) [I	=11	b6	
	Desrosiers, Betsy	b6	Hughes, E	ric b 6	T	; Jansen, Kathrin	
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	(FNIH) [T] b6	Ł Tountas, Karen (I	FNIH) [T] !	b6 Santo	s, Michael (F	NIH) [T]	
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	b6	Anderson, James (NI	H/OD) [E]	b6	; Austin, Ch	ristopher	
	(NIH/NCATS) [E]		netz, Carrie (NIH/C	DD) [E]	b6		
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	b6	Simon, Dina (NIH/O	0) [C]{ b6	Burrus-	Shaw, Cyndi (NIH/OD) [E]	
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	pen fostratton@deloit	te.comj; roiman, brett j	btolman@deloitt	e.comj; wachter, r	onathan gwa	chter@deloitte.comj	
Subject:	ACTIV mtg with Exec C	omm and WG co-chairs					
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Attendees:		Woodcock, Janet (FDA/					
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		[T]; Freire, Maria (FNIH					
		nderson, James (NIH/OE)) [E]; Austin, Chri	stopher (NIH/NCA	IS) [E]; Woline	etz, Carrie (NIH/OD)	
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Optional		I/NIAID) [C]; Conrad, Pat					
Attendees:		Protasiewicz, Ann; Thom ii, Mieko (NIH/NCI) [E]; S					
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		a; Gonzalez, Nina; Kim, E					
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	[rosalva	rez@deloitte.com]; Ar	nderson, Margaret [marganderson@deloitte.com]; Elsaid, Olivia
	-		alez, Nina [ningonzalez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Stratton, ; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]
Subject:	ACTIV n	ntg with Exec Comm ar	nd WG co-chairs
-			tomorrow morning at 8:00 AM Eastern US Time; Notes _Agenda ACTIV EC Meeting #1
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	[E]		
Optional Attendees:	Ayanna Zottoli, Dina (N	(NIH/OD) [E]; Protasie Jessica; Togashi, Mieko IH/OD) [C]; Burrus-Sha	[C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, wicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Zanellato, Ann; o (NIH/NCI) [E]; Sepulveda, Dorina (FNIH) [T]; Lagos, Enrique (NIH/NCATS) [E]; Simon, w, Cyndi (NIH/OD) [E]; Hardesty, Rebecca (NIH/OD) [C]; Alvarez, Rosa; Anderson, alez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan
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Dear TX-Clinical Master Protocol Subgroup,

Thanks,

Please find attached the materials for today's call. We will be discussing the statistical simulations the group has put together for ACTT-3, as well as we will have a presentation from the ACTG group on their outpatient master protocol.

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Stacey J. Adam, PhD Director, Cancer Research Partnerships Direct: b6	h63.3		
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	b6 ; Woodfall, Brian [JRDUS] b6 ; Van Heeswijk, Rolf [JRDBE]
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CC:	Mary Biggs b6 ; Demarcus b6 ; Macone, Erin b6
· · ·	Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]
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	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	b6 ; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Attachments:	ACTIV Therapeutics-Clinical MP Subgroup 11May2020 Meeting Guide.pdf; Adapt Out COVID Overview051120.pdf
Location:	b6

5/11/2020 6:30:00 PM End: Show Time As: Tentative Required Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo Attendees: (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Smith, David; Kim, Peter (NIH/NIAID) [E]; b6 Eron, Joe; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE] Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley Optional Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Eron, Joseph J Jr; Javan, Arzhang (NIH/NIAID) [E] Dear TX-Clinical Master Protocol Subgroup, Please find attached the materials for today's call. We will be discussing the statistical simulations the group has put together for ACTT-3, as well as we will have a presentation from the ACTG group on their outpatient master protocol. Thanks, Stacey Join Zoom Meeting b6 Meeting ID: Password: One tap mobile US (New York) **b6** US (Germantown) Dial by your location US (New York) US (Germantown) US (Chicago) US (Tacoma) US (Houston) US (San Jose)

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/11/2020 4:02:44 PM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Eisner, Mark b6 Gottesdiener, Keith b6 Hughes, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; LaVange, Lisa Levy, Elliot **b6**; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep ; Patel, Naimish [naimish.patel@sanofi.com]; Peppercorn, Amanda Poole, Mike b6 Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn b6 ; Higgs, Elizabeth (NIH/NIAID) [E] **b6** ; Garner, Carl [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy CC: Kim, Elizabeth [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd] Subject: Letter to the ACTIV Executive Committee for Group's Review Attachments: Proposal for ACTIV leaderhsip-v8.docx

Dear TX-Clinical Working Group members,

As discussed on last Thursday's call, the small writing team (Carl, Keith, Amanda, Judy, Libby, and Peter) have worked with the co-chairs to formulate the attached letter that attempted to capture the challenges and concerns that were expressed by the group.

They would now like to have the group review and comment if desired before the note is sent to the ACTIV Executive Committee tomorrow ahead of their scheduled meeting on Wednesday this week. Therefore, we would ask the group to review and send any comments they have or any edits they think absolutely critical by 9AM tomorrow (May 12). Any necessary updates will be made and then the letter will be sent on to the Executive Committee.

The team would also like to send this on behalf of the whole group with all the group members listed. **Please let us know if you are okay with this plan.**

Thank you all for your efforts and strong desire to see our remit for this partnership succeed!

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: **b6** Mobile: **b6**

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From: Hardesty, Rebecca (NIH/OD) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=21465CEB763947408D209AAABF10AF70-HARDESTYRS]

Sent: 5/11/2020 4:47:36 PM

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wood, Gretchen (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]

Subject: RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Thank you very much, Cheryl and Ashley!

 From: Melencio, Cheryl (FNIH) [T]
 b6

 Sent: Monday, May 11, 2020 12:47 PM
 To: Parker, Ashley (NIH/OD) [E]
 b6
 Wood, Gretchen (NIH/OD) [E]
 b6

Cc: Hardesty, Rebecca (NIH/OD) [C] b6

Subject: RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

I'll send her the invite and copy her assistant, Rebecca.

Cheryl Melencio

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

b6

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Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E]	b6			
Sent: Monday, May 11, 2020 12:46 PM		;=		
To: Wood, Gretchen (NIH/OD) [E]	b6	; Melencio, Cheryl (FNIH) [T]	b6	>
Cc: Hardesty, Rebecca (NIH/OD) [C]	b6			

Subject: RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Hi Gretchen and Cheryl,

Dr. Carrie Wolinetz would like to join this meeting. Cheryl – should I forward the invite or would you prefer to add on your end?

Thank you, Ashley

From: Wood, Gretchen (N	I	>		
Sent: Monday, May 11, 20	20 9:23 AM			
To: Collins, Francis (NIH/O Gary (NIH/NHLBI) [E]	D) [E] b6	;; Fauci, Anthony (NI	H/NIAID) [E] {	ь6 ; Gibbons,
Gary (NIH/NHLBI) [E]	Stof	fels, Paul b 6	; Pao, Will	iam
1.0	Dolsten, Mikael Desrosiers, Betsy >; Jansen, Kathrin Lowy, Douglas (NCI)	b6>	; Colvis, Christine (N	H/NCATS) [E]
hh	Desrosiers, Betsy	b6	j; Hughes, Eri	C
NO	>; Jansen, Kathrin	b6	; Kurilla, Michael (N	IIH/NCATS) [E]
	Lowy, Douglas (NCI)	b6 Read, S	arah (NIH/NIAID) [E]	b6 >;
Young, John Cc: Wholley, David (FNIH)	b6			
Cc: Wholley, David (FNIH)	[T] <u>b6</u>	Menetski, Joseph (FNI	H) [T] { D6	; Adam, Stacey
(FNIH) [T] b6	;; Tountas, Karen (FNIH	i) [T] b6	; Santos, Michael	(FNIH) [T]
	re, Maria (FNIH) [T]			
b6	>; Lane, Cliff (NIH/NIAID)		; Parker, Ashley (
	Anderson, James (NIH/O	b6	}; Austin,	Christopher (NIH/NCATS)
[E] b6	; Melencio, Cheryl (FNIH	'/ ['][i	
Subject: Re: Time sensitive	e ACTIV mtg with Exec C	Comm and WG co-chair	S	
Good morning,				
Please mark your calendar	s for Wednesday, May 13	s, from 8:00 AM-9:00 A	M ET for this call. A	calendar invitation will be
shared with you soon.				
With very best wishes,				
Gretchen				
From: Francis Collins	b6			
From: Francis Collins				
Date: Saturday, May 9, 2	2020 at 1:07 PM	any Faugi d	h6 "Gibb	ons Gany (NIII /NIII RI)
Date: Saturday, May 9, 2 To: Francis Collins		ony Fauci √		oons, Gary (NIH/NHLBI)
Date: Saturday, May 9, 2 To: Francis Collins [E]"	2020 at 1:07 PM b6 , Antho b6		, Gretche	
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Date: Saturday, May 9, 2 To: Francis Collins [E]" b6 b6 Betsy"	2020 at 1:07 PM b6	be (NIH/NCATS) [E]" [ughes, Eric" {	, Gretche 6 b6 b6	n Wood , "Desrosiers, , "Jansen, Kathrin"
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Date: Saturday, May 9, 7 To: Francis Collins [E]"	2020 at 1:07 PM b6 }, Antho b6 "Pao, William" { , "Colvis, Christine b6 }, "H , "Kurilla, Michael , "Read, Sarah (NIH/NIA b6 } "Mene	be (NIH/NCATS) [E]" [ughes, Eric" { (NIH/NCATS) [E]" bloom betski, Joseph (FNIH) [, "Desrosiers, , "Jansen, Kathrin" , "Lowy, Douglas g, John" , "Adam, Stacey tos, Michael (FNIH) [T]" " Parker stopher (NIH/NCATS)
Date: Saturday, May 9, 2 To: Francis Collins [E]"	b6 }, Antho b6 }, Antho b6 "Pao, William" {	be (NIH/NCATS) [E]" { ughes, Eric" { (NIH/NCATS) [E]" { NID) [E]" { to (FNIH) [T]" { to be be be be be be be be be be be be be	Gretcher b6 b6 b6	, "Desrosiers, , "Jansen, Kathrin" , "Lowy, Douglas g, John" , "Adam, Stacey tos, Michael (FNIH) [T]" " Parker stopher (NIH/NCATS)
Date: Saturday, May 9, 2 To: Francis Collins [E]"	b6 }, Antho b6 }, Antho b6 "Pao, William" {	be (NIH/NCATS) [E]" { ughes, Eric" { (NIH/NCATS) [E]" { NID) [E]" { to (FNIH) [T]" { to be be be be be be be be be be be be be	Gretcher b6 b6 b6	, "Desrosiers, , "Jansen, Kathrin" , "Lowy, Douglas g, John" , "Adam, Stacey tos, Michael (FNIH) [T]" " Parker stopher (NIH/NCATS)
Date: Saturday, May 9, 2 To: Francis Collins [E]" b6 b6 Betsy" b6 (NCI)" b6 Cc: David Wholley (FNIH) [T]" b6 [E]" b6 Subject: Time sensitive	b6 }, Antho b6 "Pao, William" { "Nead, Willia, Michael (NIH/NIA) { "Read, Sarah (NIH/NIA) { "Meno	be (NIH/NCATS) [E]" [ughes, Eric" { (NIH/NCATS) [E]" bi etski, Joseph (FNIH) [FNIH) [T]" [b6 (FNIH) [T]" b6 (FNIH) [T]" [comm and WG co-ch	Gretcher b6 b6 b6	, "Desrosiers, , "Jansen, Kathrin" , "Lowy, Douglas g, John" , "Adam, Stacey tos, Michael (FNIH) [T]" " Parker stopher (NIH/NCATS)
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Date: Saturday, May 9, 7 To: Francis Collins [E]" b6	b6 , "Kurilla, Michael , "Read, Sarah (NIH/NIA b6 , "Mene b6 , "Mene b6 , "Mene b6 , "Lane, Cliff (NIH/NIA James Anderson { ACTIV mtg with Exec of the control of the co	be (NIH/NCATS) [E]" [ughes, Eric" { (NIH/NCATS) [E]" [J, Gretcher b6 b6 b6 "Youn T]" { b6 b6 "Santarence (NIH/OD) [E] b6 J, "Austin, Christ b6 airs I am aware of some	, "Desrosiers, , "Jansen, Kathrin" , "Lowy, Douglas g, John" , "Adam, Stacey os, Michael (FNIH) [T]" r Parker stopher (NIH/NCATS) tchen Wood
Date: Saturday, May 9, 2 To: Francis Collins [E]"	b6 , "Anthombes, Anthombes, "Pao, William" { "Pao, William" { "Pao, William" { "Read, William, Michael, "Read, Sarah (NIH/NIA) b6 , "Menombes, "Tountas, Karen laria Freire b6 >, "Lane, Cliff (NIH/NIA) James Anderson { New York Melencio, Cherylamittee Members and Work Melencia is not so group members. Some	e (NIH/NCATS) [E]" [ughes, Eric" { (NIH/NCATS) [E]" NID) [E]" b etski, Joseph (FNIH) [r (FNIH) [T]" h, "Tabak, Law IAID) [E]" { b b6 I (FNIH) [T]" Comm and WG co-ch orking Group Co-Chairs: cheduled until May 20, of those focus on the r	b6 b6 b6 b6 "Youn T]" { b6 b6 "Sant rence (NIH/OD) [E] b6 , Ashley }, "Austin, Chri b6 Gre airs I am aware of some next steps for ACTIV,	, "Desrosiers, , "Jansen, Kathrin" , "Lowy, Douglas g, John" , "Adam, Stacey os, Michael (FNIH) [T]" r Parker stopher (NIH/NCATS) tchen Wood

b5

These are all very valid issues, and I believe they should be discussed by our dedicated team sooner rather than later. A meeting of the minds is particularly timely now, in the wake of a successful Leadership Team call on Wednesday and the establishment just this week of an Executive Committee to guide us moving forward. Therefore, I would like to make it a priority that the EC and the Working Group co-Chairs meet early next week to discuss and sync up on these important issues. Gretchen Wood on my staff will work with Cheryl Melencio at FNIH to reach out to you to get a suitable hourlong virtual conference set up—a morning meeting would make it easier to include Tony Fauci (because of White House duties in the afternoon) and Paul Stoffels (because of European time zones).

Thanks for all you are doing for the cause, and best regards,

Francis

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]

Sent: 5/11/2020 4:47:38 PM

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wood, Gretchen

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

 $\label{lem:condition} $$ (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]$$ Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group to the condition of the$

(FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]

Subject: RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Thanks so much, Cheryl!

CC:

From: Melencio, Cheryl (FNIH) [T] ∢	b6			
Sent: Monday, May 11, 2020 12:47 PW				
To: Parker, Ashley (NIH/OD) [E]	b6	; Wood, Gretchen (NIH/OD) [E] <	b6	
Cc: Hardesty, Rebecca (NIH/OD) [C]	b€	5		

Subject: RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

I'll send her the invite and copy her assistant, Rebecca.

Cheryl Melencio

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

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Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] {	b6			
Sent: Monday, May 11, 2020 12:46 ^เ วางา		J		
To: Wood, Gretchen (NIH/OD) [E]	b6	Melencio, Cheryl (FNIH) [T]	b6	
Cc: Hardesty, Rebecca (NIH/OD) [C] {	b6	}		
Subject: RE: Time sensitive ACTIV mtg w	vith Exec Com	nm and WG co-chairs		

Hi Gretchen and Cheryl,

Dr. Carrie Wolinetz would like to join this meeting. Cheryl – should I forward the invite or would you prefer to add on your end?

Thank you, Ashley

5	
From: Wood, Gretchen (NIH/OD) [E] b6 Sent: Monday, May 11, 2020 9:23 AM	
	ibbons
Gary (NIH/NHLBI) [E] b6 Stoffels, Paul ; Pao, William	
Dolsten, Mikael <u>b6</u> ; Colvis, Christine (NIH/NCATS) [E]	
Desrosiers, Betsy b6 Hughes, Eric	
; Jansen, Kathrin b6 ; Kurilla, Michael (NIH/NCATS) [E]	
b6 ↓ Lowy, Douglas (NCI) b6 →; Read, Sarah (NIH/NIAID) [E] 6	
Young, John 66 Cc: Wholley, David (FNIH) [T] 66 >; Menetski, Joseph (FNIH) [T] 66 }; Adam, St.	, cov
Cc: Wholley, David (FNIH) [T] b6 >; Menetski, Joseph (FNIH) [T] b6 ; Adam, Statem (FNIH) [T] b6 Santos, Michael (FNIH) [T]	icey
b6 Freire, Maria (FNIH) [T] b6 ; Tabak, Lawrence (NIH/OD) [E]	
b6 ; Lane, Cliff (NIH/NIAID) [E] b6 }; Parker, Ashley (NIH/OD) [E]	
" ht "Austin Christopher (NILL/OD) [E]	VCATS)
[E] b6 ; Melencio, Cheryl (FNIH) [T] b6 , Adstin, Christopher (MH/	,
Subject: Re: Time sensitive ACTIV mtg with Exec Comm and WG co-chairs	
Good morning,	:111 1
Please mark your calendars for Wednesday, May 13, from 8:00 AM-9:00 AM ET for this call. A calendar invitation shared with you soon.	wiii be
With very best wishes,	
Gretchen	
From: Francis Collins b6	
Date: Saturday, May 9, 2020 at 1:07 PM	
To: Francis Collins b6, Anthony Fauci b6, "Gibbons, Gary (NIH/N	HLBI)
[E]" , Gretchen Wood	
b6 , "Pao, William" (b6	
b6 "Colvis, Christine (NIH/NCATS) [E]" b6 , "Desrosie	rs,
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Betsy" b6 , "Hughes, Eric" b6 , "Jansen, Kathı b6 , "Kurilla, Michael (NIH/NCATS) [E]" b6 , "Lowy, Dol (NCI)" b6 , "Read, Sarah (NIH/NIAID) [E]" b6 , "Young, John"	ıglas
(NCI)" b6 , "Read, Sarah (NIH/NIAID) [E]" b6 , "Young, John"	
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Cc: David Wholley b6, "Menetski, Joseph (FNIH) [T]" b6, "Adam, S	tacey
(FNIH) [T]" b6 , "Tountas, Karen (FNIH) [T]" b6 , "Santos, Michael (FNIH)	I) [T]"
Maria Eroiro de "Tabak Lawronco (NIH/OD) [E]"	
> "Lane Cliff (NIH/NIAID) [F]" b6 Ashley Parker	
James Anderson b6 "Austin, Christopher (NIH/NCA	(TS)
[E]"[b6 , "Melencio, Cheryl (FNIH) [T]" b6 }, Gretchen Wood	,
b6	
Subject: Time sensitive ACTIV mtg with Exec Comm and WG co-chairs	
Dear ACTIV Executive Committee Members and Working Group Co-Chairs:	
Although our next formal ACTIV EC meeting is not scheduled until May 20, I am aware of some concerns that are voiced among our Working Group members. Some of those focus on the next steps for ACTIV, and especially about	_
implementation of the plans these groups have been working so hard to put together. b5	1

b5

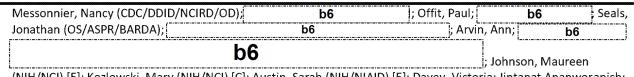
These are all very valid issues, and I believe they should be discussed by our dedicated team sooner rather than later. A meeting of the minds is particularly timely now, in the wake of a successful Leadership Team call on Wednesday and the establishment just this week of an Executive Committee to guide us moving forward. Therefore, I would like to make it a priority that the EC and the Working Group co-Chairs meet early next week to discuss and sync up on these important issues. Gretchen Wood on my staff will work with Cheryl Melencio at FNIH to reach out to you to get a suitable hourlong virtual conference set up—a morning meeting would make it easier to include Tony Fauci (because of White House duties in the afternoon) and Paul Stoffels (because of European time zones).

Thanks for all you are doing for the cause, and best regards,

Francis

From:	Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
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	[marganderson@deloitte.com]; Carluccio, Dana b6; Melencio, Cheryl (FNIH) [T]
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	[bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Kenny, Dermot b6

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	b6 ; Haynes, Barton [/o=ExchangeLabs/ou=Exchange
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Kozlowski, Mary
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	b6 ; Michael Watson (x) b6 ; Verani, Jennifer R.
	(CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject:	ACTIV Clinical Trial Capacity Working Group - reporting meeting
•	Clinical Trial Capacity Working Group Meeting Agenda_05122020.pdf
Location:	b6
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Start:	5/12/2020 3:00:00 PM
End:	5/12/2020 4:00:00 PM
Show Time As:	Tentative
Recurrence:	Weekly
	every Tuesday and Friday from 9:00 AM to 10:00 AM
Required	Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James
Attendees:	(NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley
	(NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Vincent, Mike;
	Wachtel, Jonathan; Garner, Carlos; Sizemore, Christine (NIH/FIC) [E]; Qashu, Felicia
Optional	Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E];
Attendees:	Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T]
	b6 ; Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph
	(FNIH) [T]; Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy;
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Dear Colleagues, Attached is the meeting agenda. Looking forward to a robust discussion about vaccine protocols and capacity needs! Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards, Karen

Karen H. Tountas, PhD Scientific Program Manager Foundation for the National Institutes of Health

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/11/2020 10:50:52 PM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner ; Keith Gottesdiener ; Eric Hughes **b6** ; LaVange, Lisa M Elliott Levy **b6** Menon Amanda Peppercorn]; Proschan, Michael b6 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn Frice, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael ; Wung, Peter /US **b6** ; Karen Lynn Price **b6** Pamela Tenaerts, M.D. Patterson, Amy (NIH/NHLBI) [E] b6 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Smith, David ; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Eron, Joe b6 ; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy ; Beumont-Mauviel, Maria [JRDUS] <u>b6</u>; Peeters, Monika [JRDBE]

Woodfall, Brian [JRDUS] <u>b6</u>; Van Heeswijk, Rolf [JRDBE] ; Woodfall, Brian [JRDUS] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Ghosh, Pranab Le Corre, b6 CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Eron, Joseph J Jr ्रे Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc] Subject: Follow-up from ACTIV TX-Clinical Master Protocol Subgroup #15 Attachments: ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 11May2020_Key Takeaways.pdf; ACTIV Therapeutics-Clinical_MP Subgroup_11May2020 Meeting Guide.pdf; Adapt Out COVID Overview051120.pdf

Dear TX-Clinical Master Protocol Subgroup,

Thank you all for a great call today and giving us an extra 30 minutes more than usual to allow us to hear the presentation from the ACTG group on their outpatient master protocol.

We also want to say huge thank you to Sandeep, Pranab, and Christophe for the very good and very fast simulation work that they put together for ACTT-3. All the pieces for our first trial are falling into place.

Please find attached a brief summary of the discussion and the slides once again to refer to for both the ACTT-3 progress and the ACTG study. Please keep in mind that both of these studies are pre-FDA review so we would ask that the details not be shared broadly at this time.

Thanks, Stacey

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Director, Cancer

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP] Sent: 5/11/2020 10:53:07 PM To: **b6** Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US ; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm] CC: Diamond, Michael b6 ; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy Hughes, Eric 66 } Jansen, Kathrin 🖔 Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes Rose Li Dana Carluccio Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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Dear Preclinic	al Working group me	amhers and invitees		
Jear Frechille	ar working group me	and invitees,		
Attached plea	se find the minutes f	rom Friday's meeting fo	or your review. If you find any m	nistakes, please let me know.
As part of the	action items, Michae	el Diamond and I we tas	ked with drafting a 1-2 page do	cument with information for
-			to use. I have attached a first dr	
			ect the information from potent	
			about clinical data if repurposi	
•	bout that will be help			C, C
Finally, I am a	ttaching the slides ar	nd the minutes from the	Leadership Team Meeting on 5	5/6/2020 for your review.
Best regards,				
loe				
Original A	ppointment			
	ski, Joseph (FNIH) [T]			
	, April 14, 2020 6:48			
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Dear TX-Clinical Agent Prioritization Subgroup,

In addition to the materials provided yesterday, I wanted to provide you this short description for the rational of using IL-6 inhibition in general in COVID-19 and one final point that I have been made aware of on Actemra.

RATIONALE FOR STUDYING IL-6 TREATMENT IN COVID-19 PNEUMONIA

MECHANISM OF ACTION

The pro-inflammatory, multifunctional cytokine IL-6 is produced by a variety of cell types including T cells, B cells, monocytes, fibroblasts, keratinocytes, and synovial and endothelial cells, leading to local production of IL-6 in joints affected by inflammatory processes such as rheumatoid arthritis (RA) and systemic sclerosis (SSc). It has been shown to be involved in diverse physiological processes, such as T-cell activation, B-cell differentiation, induction of immunoglobulin secretion, acute-phase protein production, stimulation of hematopoietic precursor cell growth and differentiation, osteoclast differentiation from precursor cells,

proliferation of hepatic, dermal, and neural cells, and bone and lipid metabolism (<u>Dayer and Choy 2010</u>). It exerts its effects through IL-6R, which is present both in soluble and in membrane-expressed forms.

Two distinct subphenotypes, a hypo-inflammatory (class 1) and hyper-inflammatory subphenotype (class 2), have been identified in acute respiratory distress syndrome (ARDS), a common and frequently fatal cause of respiratory failure among critically ill patients. The hyper-inflammatory subphenotype has higher values of sTNFr-1 and IL-6, lower platelet counts and more vasopressor use. In a 539 patient study investigating the treatment of simvastatin vs placebo, the hyper-inflammatory subphenotype had a higher mortality, fewer ventilator-free and organ failure-free days. (Calfee et al 2018 and Calfee et al. 2014). IL-6 could be a characteristic of an "inflammatory endotype" of ARDS and potentially could be target for the treatment of severe and critical COVID-19.

GM-CSF and IL-6 are the key cytokines leading to inflammatory storm which may result in increased alveolar-capillary blood-gas exchange dysfunction, especially impaired oxygen diffusion, and eventually lead to pulmonary fibrosis and organ failure. Their research suggests that IL-6 might play a key role in this process and interfering of IL-6 might be a potentially therapeutic for severe and critical COVID-19.

NOTE: Actemra (TCZ) is the only IL-6 blocker approved for the treatment of CAR-T related cytokine release syndrome.

Thanks again for your consideration of this request.

Stacey

Stacey J. Adam, PhD Director, Cancer Research Partnerships

Direct: **b6** Mobile: **b6**

From: Adam, Stacey (FNIH) [T]

Sent: Monday, May 11, 2020 10:33 PM

Subject: Material for ACTIV TX-Clinical Agent Prioritization Subgroup #9

Dear TX-Clinical Agent Prioritization Subgroup,

We are looking forward to our meeting with you all tomorrow. For the meeting tomorrow, we have to goals:

- 1. We would like to get your feedback on the updated design for the prioritization criteria, weighting, and staging. The new model, which we have still tried to keep simple so has not to overcomplicate the process can be found in the slides for your review.
- 2. We will be considering an request from one of the ACTIV participating companies. There has been a request that ACTIV consider aiding with accrual to one of the IL-6 Inhibitor (Actemra) studies from Roche. This request has been made because the company has seen a recent decline in accrual due to a slowing of COVID cases in the US and due to a number of competing studies. While no promises have been made, the ACTIV Leadership did ask this team to consider the request. Upon review of the request, the co-chairs felt it was right for us to consider for the following reasons:
 - During our initial discussions, our group found IL-6 inhibitors to be a high priority target, but triaged them from our study due to the fact that we thought other well-designed trials were being conducted. Since this may no longer be the case, we wished to reconsider how we might facilitate this high priority target.

- It will benefit patients if we can get at least one of the larger trials in this class to completion so the data can be reviewed by the FDA. If determined to be a valid treatment for COVID-19, this would give us one more option for treatment.
- The company was willing to let us review the portfolio of all of the IL-6 inhibitors being tested, and only say yes to assisting them if we thought that Actemra was the best option for patients and getting a valuable treatment to them quickly.

To assist this group with this last point, I have put together a very quick summary of either the existing clinical data or preclinical data for one and links to the safety and DDI profiles for each compound. I am hoping that this will aide in your deliberations I this matter. (see attached document) We will also be receiving additional rationale information.

It is important to note that Roche is not asking for any funding, but merely help in identifying sites that would be capable of opening their trial to accelerate its accrual. If our group determines that Actemra is the most appropriate choice of IL-6 inhibitors and that IL-6 inhibition remains a high priority target, we will refer Roche to our Clinical Trial Capacity WG to have them assist in site identification.

One note: We do understand that if we choose to do this we will be putting one more trial in the same space as our master protocol, so that should likely be factored into the discussion.

Thank you all in advance for your consideration of these two topics. We look forward to a fruitful discussion tomorrow.

Best, Stacey	
Stacey J. Adam, PhD Director, Cancer Research Partnerships Direct: b6 Mobile: b6	
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From:	Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASI	(H]
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CC:	Wachtel, Jonathan [jwachtel@deloitte.com]	
Subject:	RE: ACTIV Clinical Trial Capacity Working Group - reporting meeting	
Attachments:	nts: Clinical Trial Capacity Working Group Meeting Agenda_05122020.pdf	
Dear Colleage	eagues,	
	ck reminder that our working group meeting today (Tuesday, May 12) is scheduled for 11: Friday, we will resume our usual WG meeting time. Apologies for any confusion this has	
Looking forw	orward to talking with you soon.	
Karen		
Original A	al Appointment	
_	ıntas, Karen (FNIH) [T]	
	sday, April 14, 2020 5:00 PM	
	ct: ACTIV Clinical Trial Capacity Working Group - reporting meeting	
Where:	esday, May 12, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).	
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Apologies for the repeat emails, updated agenda is attached. Karen

Dear Colleagues, Attached is the meeting agenda. Looking forward to a robust discussion about vaccine protocols and capacity needs! Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards, Karen

Karen H. Tountas, PhD Scientific Program Manager Foundation for the National Institutes of Health

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Attachments:	Proposal for A	ACTIV leaderhsip-	vF 051220.pdf			
Dear TX-Clinic	al Working G	iroup members,				
Please find at	tached the fir	nal version of the	e letter that will go to	the ACTIV Exe	cutive Committee shortly.	
Thank you all	for your revie	ew,				
Stacey	,	,				
J. Good						
Stoom T Ad	., ,,,					
Stacey J. Ad						
Director, Can						
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From: Adam, Stacey (FNIH) [T]

Sent: Monday, May 11, 2020 12:03 PM

Subject: Letter to the ACTIV Executive Committee for Group's Review

Dear TX-Clinical Working Group members,

As discussed on last Thursday's call, the small writing team (Carl, Keith, Amanda, Judy, Libby, and Peter) have worked with the co-chairs to formulate the attached letter that attempted to capture the challenges and concerns that were expressed by the group.

They would now like to have the group review and comment if desired before the note is sent to the ACTIV Executive Committee tomorrow ahead of their scheduled meeting on Wednesday this week. Therefore, we would ask the group to review and send any comments they have or any edits they think absolutely critical by 9AM tomorrow (May 12). Any necessary updates will be made and then the letter will be sent on to the Executive Committee.

The team would also like to send this on behalf of the whole group with all the group members listed. **Please let us know if you are okay with this plan.**

Thank you all for your efforts and strong desire to see our remit for this partnership succeed!

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: **b6** Mobile: **b6**

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852





From:	Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
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	b6 Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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	b6 ; Dolsten, Mikael b6
CC:	Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
	b6 Hughes, Eric b6 Read, Sarah (NIH/NIAID) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Jansen, Kathrin
	b6 ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NIH/NCI)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Young, John
	b6 ; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E]
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	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher
	(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Wolinetz, Carrie (NIH/OD)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject:	FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group
Attachments:	Proposal for ACTIV leaderhsip-vF 051220.pdf
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D 40TU/F	
	recutive Committee Members:
	e attached letter from the ACTIV Therapeutics-Clinical Working Group received this morning, for
	on tomorrow morning's Executive Committee teleconference. While we expect the proposals contained
herein will be	one major topic of discussion, the purpose of the meeting is to hear from all of the Working Group co-
chairs (copied	on this note) regarding what is working and where they may be facing challenges in ACTIV, and jointly
discuss strate	gy moving forward.
David	
	Stacey (FNIH) [T] b6
	, May 12, 2020 9:52 AM
To: Wholley,	David (FNIH) [T] 6
Cc: Read, Sara	h (NIH/NIAID) [E] b6 Eric Hughes b6 ; Carlos O Garner
-	b6 ; Judy Currier b6 Keith Gottesdiener
	b6 >; Amanda Peppercorn b6 ; Stein, Peter (FDA/CDER)

,			
d b6	Higgs, Elizabeth (NIH/NIAID) [E]	b6	elkim@deloitte.com
Subject: Letter to the	ACTIV Executive Committee from the Therap	eutics-Clinic	cal Working Group

Hi David,

Please find attached a letter from the Therapeutics-Clinical Working Group to the ACTIV Executive Committee for their consideration. Overall, the letter is meant to relate some broad challenges and issues that the Therapeutics-Clinical group thinks the ACTIV PPP is facing, as well as some very specific requests for assistance from the ACTIV EC for our team.

Please relay this to the ACTIV EC for their review. Our group would welcome any feedback they have.

Thanks, Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

Direct: 66 Mobile: 66

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852





From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC] 5/12/2020 2:58:32 PM Sent: To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Hudson, Thomas James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David Henetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Pangalos, Mene Paul, Steve b6

b6 ; Rasi, Guido b6 Plump, Andy b6
Reed, John b6 Rouse, Doris Perlmutter, Roger [(FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel j; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Tsai, John [john.tsai@novartis.com]; Vessey, Rupert b6 ; Virgin, Skip b6 } Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John b6 ; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy ; Hughes, Eric b6 ; Jansen, Kathrin ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Kim, Elizabeth [elkim@deloitte.com]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan

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	jwachtel@deloitte.com]; Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group	
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	b6 ; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange	
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	T] [/o=ExchangeLabs/ou=Exchange Administrative Group	•
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	b6 ; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group	
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	/o=ExchangeLabs/ou=Exchange Administrative Group	
	FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; FNIH Central Account	
	FNIH@roseliassociates.com]; Li, Rose 66 ; Zottoli, Jessica 66	
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group	
	FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Gladman, Jordan (NIH/C	D)
	E] [/o=ExchangeLabs/ou=Exchange Administrative Group	
	FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]; Elsaid, Olivia	
	oelsaid@deloitte.com]; Castillejos zenteno, Carlos [JRDUS] b6 ; Dimishkov, Roxanne (NIH/NHLI	31)
	C] [/o=ExchangeLabs/ou=Exchange Administrative Group	•
	FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]	
Subject:	ACTIV Response Partnership Leadership Team Meeting #4	
ocation:		
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Start:	5/3/2020 4:00:00 PM	
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Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Freire, Maria (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez,

Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Rachel Ramoni; Plenge, Robert; Talley, Michael; william.lee@gilead.com; Cavaleri, Marco; Messonnier, Nancy

(CDC/DDID/NCIRD/OD); Gibbons, Gary (NIH/NHLBI) [E]

Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Simon, Dina (NIH/OD) [C]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]; FNIH Central Account; Li, Rose; Zottoli, Jessica; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Elsaid, Olivia; Castillejos zenteno, Carlos [JRDUS]; Dimishkov, Roxanne (NIH/NHLBI) [C]

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	Freire, Maria (FNIH) [T]		} Wo	olinetz, Carrie			b6	; Austin,	
	Christopher (NIH/NCAT	· · · L	b6			(NÌH/OD) [E]	Γ	b6];
	Lane, Cliff (NIH/NIAID)	[E][b6	Gadbois, El			b6		i Viïchelle
	(NIH/OD) [E] [b6		, Gary (OS/AS			b6	Marks, Pe	eter
	(FDA/CBER)	b6	; Wood	lcock, Janet (F	DA/CDER)	[/o=Exchang	eLabs/ou=E	xchange	
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CC:	Adam, Stacey (FNIH) [T	~		arez, Rosa [ro					
	[marganderson@deloit								
	James, Stephanie (FNIF	I) [T] [b6	; Kim, Elizabet					
		Santos, Mich				Stratton, Ben	[bstratton(@deloitte.cor	n];
	Tolman, Brett [btolman	@deloitte.c	om]; Tounta	as, Karen (FNI	H) [T] [b6	Wachte	el, Jonathan	
	[jwachtel@deloitte.cor	n]; Barasch,	Kimberly (N	IH/NIAID) [C]		b6	; Conr	ad, Patricia	
	(NIH/NIAID) [E]	b6]; Dim	ishkov, Roxar	ne (NIH/N	HLBI) [C]	b	6	
	McManus, Ayanna (NIF	1/OD) [E]	b	6	; Protasiev	wicz, Ann		b6	}
	Thomas, Ashley (FDA/C	DER)	b6		Wood, Gre	tchen (NIH/	OD) [E]	b6	;;
	Zanellato, Ann	b6	; Burrus-	Shaw, Cyndi (I	VIH/OD) [E] [b6	Simo	n, Dina
	(NIH/OD) [C]	b6	Li, Rose	b	6	FNIH C	entral Accou	unt	
	[FNIH@roseliassociates	.com]; Aww	 ad, David (1	NIH/NIAID) [C]		b6	; Zottoli,	Jessica	
	b6	; Togas	hi, Mieko (N	IIH/NCI) [E][^-		b6	; Sepu	ılveda, Dorina	a (FNIH)
	[T] [b6	Hardest	ty, Rebecca	(NIH/OD) [cˈ] <u>[ˈ</u>		b6	Lagos	, Enrique	
	(NIH/NCATS) [E]	b6]; Carv	er, Trea (NIH ['])	[C]	b6	Üowy, [Douglas (NIH/	NCI) [E]
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Required Attendees:

Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Pao, William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Freire, Maria (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Anderson, James (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Marks, Peter (FDA/CBER)

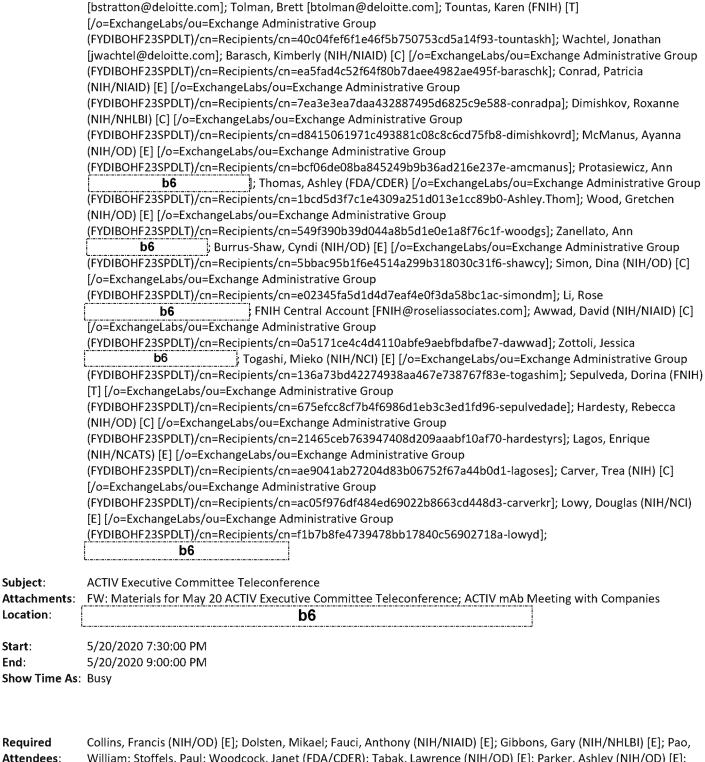
Optional Attendees:

Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood,

Central Account; Awwad, David (NIH/NIAID) [C]; Zottoli, Jessica; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, Dorina (FNIH) [T]; Hardesty, Rebecca (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Carver, Trea (NIH) [C]; Lowy, Douglas (NIH/NCI) [E]; Cheryl Melencio is inviting you to a scheduled Zoom meeting. Join Zoom Meeting b6 Meeting ID: Password: b6 One tap mobile US (New York) **b6** US (Germantown) Dial by your location US (New York) US (Germantown) US (Chicago) US (San Jose) US (San Jose) US (Tacoma) US (Houston) Meeting ID Password **b6 b6** Find your local number:

Gretchen (NIH/OD) [E]; Zanellato, Ann; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Li, Rose; FNIH

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC] Sent: 5/12/2020 3:09:01 PM To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dolsten, Mikael ; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Pao, William b6 Tabak, Lawrence (NIH/OD) [E] ; Stoffels, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy b6 Hughes, Eric b6 Jansen, Kathrin ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group b6 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John ]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc] CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [ningonzalez@deloitte.com]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben



Required Attendees: William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Freire, Maria (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Anderson, James (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Marks, Peter (FDA/CBER)

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Zanellato, Ann; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Li, Rose; FNIH

			essica; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, e (NIH/NCATS) [E]; Carver, Trea (NIH) [C]; Lowy, I	
Cheryl Mele	encio is inviting you to a sc	heduled Zoom meeting.		
Join Zoom I	Vleeting			
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<u></u>	US (Houston)			
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From:	Woodcock, Janet	,	j			
Sent:	5/12/2020 5:45:3					
То:	· · · · · · · · · · · · · · · · · · ·		-	_	ministrative Group	
Subject:	•				e50d2ff0b6c2-collir itics-Clinical Workir	-
Subject.	NE. Letter to the /	ACTIV EXECUTIVE CO	Jiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiii	ine merapeu	itics-cillical Workii	ig Group
Flag:	Follow up					
Will call at 5	. Thanks. jw					
From: Collin	s, Francis (NIH/OD	) [E] <b>b</b> 6	6			
Sent: Tuesd	ay, May 12, 2020 1	:31 PM				
To: Woodco	ck, Janet	D6		T-1		
Subject: RE:	Letter to the ACTI	v Executive Com	imittee from ti	ne Therapeu	itics-Clinical Work	ing Group
5 pm?	<b>b6</b> if you	can. Otherwis	se after 7 pm	is good		
From: Wood	dcock, Janet	b6				
Sent: Tuesd	ay, May 12, 2020 1 Francis (NIH/OD) [[	:08 PM				
To: Collins, I	-rancis (NIH/OD) [B	.][ b6		Tl		in a Consum
Subject: RE:	Letter to the ACTI	V Executive Com	imittee from ti	ne Therapeu	itics-Clinical Work	ang Group
No have to l	orief higher ups. L	ater better. Jwv				
Date: May 1 To: Woodco Subject: RE:	s, Francis (NIH/OD 2, 2020 at 12:49:3 ck, Janet Letter to the ACTI d like that. Can y	2 PM EDT  b6  V Executive Com		ne Therapeu	ıtics-Clinical Work	cing Group
From: Wood	dcock, Janet	b6	1			
	ay, May 12, 2020 1					
	Francis (NIH/OD) [[	(				
	: Letter to the ACT	L	 nmittee from 1	he Therane	utics-Clinical Wor	king Group
	uss before tomorro			.ne merape	uutaa ammaa wa	ining or out
From: Whol	ley, David (FNIH) [	[□] <b>b6</b>				
	ay, May 12, 20 <u>20 1</u>			۶		·
	rancis S (NIH)	b6	; Stoffels, Pa	iul [JJCUS] {	b6	; Fauci, Anthony S (NIH)
b	i; Gibbo	ons, Gary H (NIH)	b	3	Woodcock, Jane	
	<b>b6</b>	Pao, William			>; Dolsten, Mikae	<u> </u>
Cc: Colvis, C	hristine M (NIH)		>; Desi	osiers, Bets	у	<b>b6</b> ; Hughes,
Eric {	b6	; Read, Sarah	W (NIH)	he	Jansen, k	
``	b6	Kurilla, Michael	G (NIH) ₹	b6		Douglas R (NIH)
b6	>; Young		b6		e, Maria C (NIH)	<b>b6</b> ; Tabak,
Lawrence A	(NIH) à	h6 !-	Lane Henry C	(NIH)!	h6	Darker Achley S/NILL

he	>: Anderson, James M (NIH)	b6	; Austin, Christopher P (NIH)			
b6	>; Anderson, James M (NIH) ; Wolinetz, Carrie D (NIH)	b6				
Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group						
Dear ACTIV Executiv	ve Committee Members:					

Please see the attached letter from the ACTIV Therapeutics-Clinical Working Group received this morning, for consideration on tomorrow morning's Executive Committee teleconference. While we expect the proposals contained herein will be one major topic of discussion, the purpose of the meeting is to hear from all of the Working Group cochairs (copied on this note) regarding what is working and where they may be facing challenges in ACTIV, and jointly discuss strategy moving forward.

David

From: Adam, Stacey (FNIH)	[T] <b>b6</b>					
Sent: Tuesday, May 12, 202	20 9:52 AM					
To: Wholley, David (FNIH) [	T] 66	}	-			
Cc: Read, Sarah (NIH/NIAID	) [E] [	b6	Eric Hughes		b6	; Carlos O Garner
b6	; Judy Currier	<u></u>	b6	···-; Keith G	ottesdiener	
↓b6	, Amanda	Peppercorn		b6	St	ein, Peter (FDA/CDER)
b6	Higgs, Elizabetl	า (NIH/NIAI	) [E]	b6	; elkim@	deloitte.com
Subject: Letter to the ACTIV	/ Executive Com	mittee from	the Therapeut	ics-Clinical '	Working Gro	pup

Hi David,

Please find attached a letter from the Therapeutics-Clinical Working Group to the ACTIV Executive Committee for their consideration. Overall, the letter is meant to relate some broad challenges and issues that the Therapeutics-Clinical group thinks the ACTIV PPP is facing, as well as some very specific requests for assistance from the ACTIV EC for our team.

Please relay this to the ACTIV EC for their review. Our group would welcome any feedback they have.

Thanks, Stacey

Stacey J. Adam, PhD Director, Cancer

Research Partnerships

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

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From: Sent:	Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF] 5/12/2020 6:02:20 PM
Subject: Attachments: Location:	*Call with Dr. Janet Woodcock image001.jpg; image002.jpg; image004.jpg; image005.png She will dial you on your iPhone
Start: End: Show Time As:	5/12/2020 9:00:00 PM 5/12/2020 9:10:00 PM Busy
Recurrence:	(none)
Will call at 5. ⁻	Γhanks. jw
From: Collins.	Francis (NIH/OD) [E] <b>b6</b>
	y, May 12, 2020 1:31 PM
To: Woodcock	c, Janet b6
Subject: RE: L	etter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group
t	b6 if you can. Otherwise after 7 pm is good
From: Woods	ock, Janet <b>b6</b>
Sent: Tuesday	, May 12, 2020 1:08 PM
<b>To:</b> Collins, Fr	ancis (NIH/OD) [E] < b6
	etter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group
•	
No have to br	ief higher ups. Later better. Jwv
	Francis (NIH/OD) [E] <b>b6</b>
Date: May 12,	, 2020 at 12:49:32 PM EDT
Subject: RF: L	ς, Janetb6 etter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group
Subject. NE. E	etter to the Acriv Exceptive committee from the merupeaties chilical working group
Yes, I would	like that. Can you do 3:30?
From: Woodc	ock, Janet <b>√ b6</b>
Sent: Tuesday	, May 12, 2020 11:28 AM
	ancis (NIH/OD) [E] 66
Subject: FW: I	Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group
Can we discus	ss before tomorrow? jw
From: Wholle	y, David (FNIH) [T] <b>b6</b>
	, May 12, 2020 10:46 AM
	ancis S (NIH) <b>b6</b> ; Stoffels, Paul [JJCUS] <b>b6</b> ; Fauci, Anthony S (NIH)

b6	╞; Gibbons, Gary H (N	nn	:	cock, Janet	
b6	; Pao, Willia	am {	>; Dols	ten, Mikael	
c: Colvis, Christine M	l (NIH) [ <b>b</b> 6	; Desrosie	rs, Betsy	b6	: Hughe
ric b6		ah W (NIH) ₹	·	; Jansen, Kathrin	
b6	; Kurilla, Micha	· · · · · · · · · · · · · · · · · · ·	b6	; Lowy, Douglas F	R (NIH)
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awrence A (NIH)	b6	Lane, Henry C (NIH	) < b6	Parker,	Ashley S (NIH)
b6	>; Anderson, James	` <u>'                                   </u>	b6	; Austin, Christo	pher P (NIH)
	Wolinetz, Carrie D		}		
<b>ıbject:</b> FW: Letter to	the ACTIV Executive (	Committee from the T	herapeutics-C	linical Working Gro	up
	jor topic of discussion, note) regarding what i ng forward.		-		
avid					
From: Adam, Stacey ( Sent: Tuesday, May 1 Fo: Wholley, David (Fi Cc: Read, Sarah (NIH/	2, 2020 9:52 AM  NIH) [T] b6  NIAID) [E] b  ; Judy Currier [  }; Amanda I	b6 Peppercorn[ I (NIH/NIAID) [E]	Keith b6	b6	Carlos O Garner Peter (FDA/CDER)
•	ACTIV Executive Com	mittee from the mera	peutics-cirrica	ar working Group	
li David,					
onsideration. Overa	letter from the Thera III, the letter is meant t V PPP is facing, as well	to relate some broad	challenges and	lissues that the Th	erapeutics-Clinical
lease relay this to th	e ACTIV EC for their re	view. Our group wou	ld welcome ar	y feedback they ha	ave.
hanks, tacey					
Stacey J. Adam, PhI	•				

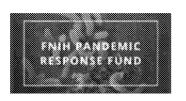
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852 

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD] Sent: 5/13/2020 1:57:04 AM To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dolsten, Mikael ; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Pao, William b6 Stoffels, Paul [JJCUS] b6 Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (EYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy Hughes, Eric b6 ; Jansen, Kathrin b6 Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Wolf-Rodda, Julie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89f0a08ab7224e0b9dc5a118ff336aff-wolfrodj]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d] CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs] Subject: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time Attachments: Agenda ACTIV EC Meeting #1 5-13-20.docx; Proposal for ACTIV leaderhsip-vF 051220.pdf

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the agenda for our meeting tomorrow morning (via Zoom) and a copy of the letter from the Therapeutics- Clinical Working Group you received earlier today, for our discussion.

Please let Joe Menetski or Cheryl Melencio know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley Senior Vice-President, Research Partnerships Foundation for the National Institutes of Health

b6

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]							
Sent:	5/13/2020 1:58:34 AM							
To:	Eric Hughes b6 Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange							
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa];							
	Ruxandra Draghia-Akli <b>b6</b> Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative							
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel							
	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John							
	b6 ]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike							
	b6 ]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange							
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];							
	Vincent, Michael <b>b6</b> ; Keith Gottesdiener <b>b6</b> ; Elliott Levy							
	b6 Wung, Peter /US b6 Koroshetz, Walter (NIH/NINDS) [E]							
	[/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth							
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner							
	b6 Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]							
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative							
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa							
	Maria [rosalvarez@deloitte.com]; Salathin, Carla <b>b6</b>							
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]							
	[/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)							
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon  b6 : Walker, Paula (NIH/NINDS) [F] [/o=Exchange] abs/ou=Exchange							
	timer) radia (m. ) transport Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or Exertain Secarety or E							
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]							
Subject:	Initial Follow-up from ACTIV TX-Clinical Agent Prioritization Subgroup #9							
Attachments:	ACTIV_Therapeutics-Clinical_AP Sub-Group Meeting 12May2020 Key Takeaways.pdf							
Actacimients.	ACTIV_THE apedites-clinical_Ar Sub-Gloup Meeting 12May2020 Key Takeaways.pul							

Dear TX-Clinical Agent Prioritizaiton Subgroup,

Thank you so much for another meeting with great feedback to refine the process. Elizabeth and I will work to incorporate your additional changes to the scoring and weighting. In addition, I am looking into the additional resources that the group was requesting.

For now please find some high level action items and notes that Elizabeth was kind enough to capture. I will follow-up with the formal summary to the meeting in the next 24 hours or so.

As always, if you have any questions, please do not hesitate to contact us.

Thanks, Stacey

**Stacey J. Adam, PhD**Director, Cancer

Research Partnerships

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Direct:		b6		Mol	oile: 🗀	b6		
fnih.org	L							
		Pike,	Suite	600,	North	Bethesda,	MD	20852



From:

Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]

Sent:

5/13/2020 2:03:51 AM

To:

Stoffels, Paul [ b6 ]

CC:

Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

Subject:

FW: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time

Attachments: Agenda ACTIV EC Meeting #1 5-13-20.docx; Proposal for ACTIV leaderhsip-vF 051220.pdf

## Hi Paul,

I understand from David Wholley that you will be able to join the ACTIV ExComm call tomorrow – I am really glad to have your co-leadership for this important discussion.

Can I ask you to make brief opening remarks at the outset, and also to help me summarize at the end?

### Many thanks, Francis

From: Wholley, David	l (FNIH) [T]	b6	<u> </u>						
Sent: Tuesday, May 1									
To: Collins, Francis (N	IIH/OD) [E] ·	b6		; Dolsten, I	Mikael	k	)6	]; Fauci, <i>F</i>	Anthony
(NIH/NIAID) [E]	b6	; Gibb	ons, Gary	/ (NIH/NHLI	3I) [E][	b6	; Pao	, William	
b6	; Stoff	els, Paul [JJC	US] {	b6	>; W	/oodcock, J	anet (FDA/CDE	:R)	
b6		; Colvis, Chri	stine (NIF	H/NCATS) [E	<b>[</b> ]	b6	}; Desro	siers, Bets	sy
b6		; Hughes	, Erid	b	6	Janse	n, Kathrin		
b6	Kı	ırilla, Michae	el (NIH/NO	CATS) [E]		b6	Lowy, Dou	ıglas (NIH	/NCI) [E]
b6	: Read. Sa	rah (NIH/NIA	(ID) [E] [	b6		: Young, Jo	ohn		
b6	; N	1enetski, Jos	eph (FNÏF	1) [T]	b6	; Ada	m, Stacey (FNI	H) [T]	
j D6 ; I	ountas, Kar	en (FNIH) [ I j		<b>b</b> 6	i; Santos,	, Michael (F	·NIH) [I] į	b6	;
Freire, Maria (FNIH) [	T][	b6	Tabak, La	wrence (NI	H/OD) [E] [		b6	]; Lane, (	liff
(NIH/NIAID) [E] (NIH/OD) [E]	b6	Parke	r, Ashley	(NIH/OD) [	E]	b6	}; Anders	ion, Jame	s
(NIH/OD) [E]	b6	>; A	ustin, Chr	ristopher (N	IIH/NCATS	) [E	b6	Wolf-	-Rodda,
Julie (LIVILI) [1] [	Do	GOII	aiez, miii	a Chingoniza	alez@delo	itte.com>			
Cc: Melencio, Cheryl	(FNIH) [T]	b6	·	; Wood, Gre	etchen (NII	H/OD) [E]	b6		
Subject: Agenda for A	ACTIV EC me	eting tomor	row morr	ning at 8:00	AM Easte	rn US Time			
Importance: High									

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the agenda for our meeting tomorrow morning (via Zoom) and a copy of the letter from the Therapeutics- Clinical Working Group you received earlier today, for our discussion.

Please let Joe Menetski or Cheryl Melencio know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley Senior Vice-President, Research Partnerships Foundation for the National Institutes of Health



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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP							
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Sent:	5/13/2020 2:37:49 AM							
To:	Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan							
	[/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva							
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier							
	[/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo							
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner							
	b6     Keith Gottesdiener     b6     Eric Hughes       b6     LaVange, Lisa M     b6     Elliott Levy     b6     Sandeep       Menon     b6     Amanda Peppercorn     b6     Proschan, Michael       (NIH/NIAID)     [Context)     Froschan, Michael       (NIH/NIAID)     [Context)     Froschan, Michael							
	b6 ; LaVange, Lisa M b6 ]; Elliott Levy b6 ; Sandeep  Menon! b6 : Amanda Penpercorn b6 ; Proschan Michael							
	b6     ; LaVange, Lisa M     b6     ]; Elliott Levy     b6     ; Sandeep       Menon     b6     ]; Amanda Peppercorn     b6     ]; Proschan, Michael       (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID)							
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn    b6   Price Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group							
	1							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B.							
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li							
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER)							
	[/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI)							
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael							
	b6 ; Wung, Peter /US b6 Karen Lynn Price b6 Pamela Tenaerts, M.D. b6 ; Patterson, Amy (NIH/NHLBI) [E]							
	b6 Pamela Tenaerts, M.D. b6 ; Patterson, Amy (NIH/NHLBI) [E]							
	/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth							
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy							
	b6 ; Beumont-Mauviel, Maria [JRDUS] b6 ; Peeters, Monika [JRDBE] b6 ; Woodfall, Brian [JRDUS] b6 ; Van Heeswijk, Rolf [JRDBE]							
	<b>b6</b> ; Woodfall, Brian [JRDUS] <b>b6</b> ; Van Heeswijk, Rolf [JRDBE]							
	, 50							
CC:	Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan							
	[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]							
	[/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]							
	[/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]							
Subject:	Materials for ACTIV TX-Clinical Master Protocol Subgroup Meeting #16							
Attachments:	ACTIV Therapeutics-Clinical_MP Subgroup_13May2020 Meeting Guide.pdf							

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the slides for our portion of the meeting tomorrow. The presentation slides from I-SPY will be shared on the call from their group.

We are going to try to keep the I-SPY presentation to no more that 40 minutes, including questions so we can discuss a few necessary matters for next steps on our trials.

Stacey
Stacey J. Adam, PhD Director, Cancer Research Partnerships Direct: b6   Mobile b6
oin Zoom Meeting
<b>b</b> 6
Meeting ID: b6 Password: b6 One tap mobile US (Chicago) US (New York)
Dial by your location
US (Chicago) US (New York) US (Germantown) US (San Jose) US (San Jose) US (Tacoma) US (Houston)  Meeting ID: b6
Find your local number: <b>b6</b>
L

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]

**Sent**: 5/13/2020 10:46:49 AM

To: Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]

Subject: Fwd: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time

Attachments: Agenda ACTIV EC Meeting #1 5-13-20.docx; ATT00001.htm; Proposal for ACTIV leaderhsip-vF 051220.pdf;

ATT00002.htm

### Begin forwarded message:

		L.C.	)		
From: "Wholley, David (Fl	NIH) [T]" {	b6			
<b>Date:</b> May 12, 2020 at 9:5					
To: "Collins, Francis (NIH/	OD) [E]" 🚛	b6	,."Dolsten, Mikae	el"	
b6	"Fauc	i, Anthony (NIH/N	IAID) [E]"[	b6	៊ុ, "Gibbons, Gary
(NIH/NHLBI) [E]"	b6	"Pao, Williar	უ" <b>ქ b</b> 6	j	'Stoffels, Paul
[JJCUS]" b6	]"Wd	oodcock, Janet (FD	A/CDER)"	b6	
"Colvis, Christine (NIH/NC	:ATS) [E]" [	b6	"Desrosier	s, Betsy"	
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b6	, "Kurilla	a, Michael (NIH/N	CATS) [E]" [	b6	}, "Lowy,
Douglas (NIH/NCI) [E]"	b6	, "Read, S	arah (NIH/NIAID)	[E]	
Douglas (NIH/NCI) [E]" "Young, John" {	b6	"Menetsk	ki, Joseph (FNIH) [T	]"	<b>16</b>
"Adam, Stacey (FNIH) [T]"	b6	"Tountas	, Karen (FNIH) [T]"	' < <u>'</u>	JU
"Santos, Michael (FNIH) [	Γ]" ∢	b6 ]"Frei	ire, Maria (FNIH) [7	г]"	
"Santos, Michael (FNIH) [ "Tabak, Lawrence (NIH/O	D) [E]"[	b6	"Lane, Cliff (	NIĤ/NIAID) [E	]"
b6 , "	Parker, Ashl	ey (NIH/OD) [E]" {	b6	"Ande	rson, James
(NIH/OD) [E]" {	b6	"Austin, Ch	ristopher (NIH/NC	CATS) [E]"	
<b>b6</b>	"Wolf-Rodd	a, Julie (FNIH) [T]"	b6	"Gonz	alez, Nina"
_ <ningonzalez@deloitte.co< td=""><td></td><td></td><td></td><td></td><td></td></ningonzalez@deloitte.co<>					
Cc: "Melencio, Cheryl (FN	IH) [T]"	b6	"Wood, Gretche	n (NIH/OD) [E	]"
b6	· · · · · · · · · · · · · · · · · · ·				

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Please let Joe Menetski or Cheryl Melencio know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
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Inh.org

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]

**Sent**: 5/13/2020 11:19:33 AM

To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]

CC: Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]

Subject: Fwd: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time

Attachments: Agenda ACTIV EC Meeting #1 5-13-20.docx; ATT00001.htm; Proposal for ACTIV leaderhsip-vF 051220.pdf;

ATT00002.htm

For 8am ACTIV EC Meeting if you want to read ahead.

Thanks, Ashley

### Begin forwarded message:

From: "Wholley, David (FN	IH) [T]" -	k	6				
Date: May 12, 2020 at 9:57	':04 PM	EDT					
To: "Collins, Francis (NIH/C	D) [E]"[		b6	Dolsten, Mika	ael"		
b6	, "Fa	uci, Antho	ny (NIH/NI	AID) [E]"	b6	}, "(	Gibbons, Gary
[JJCUS]"[ b6 [JJCUS]"[ b6	b6	, "ו	Pao, Williar	n" b	6	, "Stof	fels, Paul
[JJCUS]" <u>b6</u>		Woodcock	, Janet (FD	A/CDER)"	I	o6	
"Colvis. Christine (NIH/NCA	\TS) [E]"		b6	"Desrosie	ers. Betsv	.11	
b6		_, "Hughe	es, Eric"	b6		į, "Jansen,	Kathrin"
† <b>b</b> 6	, "Kur	ʻilla, Micha	ael (NIH/NO	CATS) [E]"[	b6		ِيٰ "Lowy,
Douglas (NIH/NCI) [E]" "Young, John" "Adam, Stacey (FNIH) [T]"	b(	 3	¨, "Read, S	arah (NIH/NIAID)	) [E]"	b6	
"Young, John"	b6		]"Menetsk	ki, Joseph (FNIH)	[T]"[	b6	
"Adam, Stacey (FNIH) [T]"	Ī	o6	"Tountas	, Karen (FNIH) [T	]"[	b6	]
"Santos, Michael (FNIH) [T]	" [	b6	;"Frei	re, Maria (FNIH)	[T]"	b6	,
"Tabak, Lawrence (NIH/OD	) [E]" [		b6	"Lane, Cliff	(NIH/NIA	(ID) [E]"	
<b>b6</b> , "Pa	arker, As	hley (NIH,	/OD) [E]"	b6	, '	'Anderson	, James
(NIH/OD) [E]"[	b6	],	"Austin, Ch	ristopher (NIH/N	ICATS) [E	<b> </b> "	
b6 "\	Wolf-Ro	dda, Julie	(FNIH) [T]"	b6		"Gonzalez	, Nina"
<ningonzalez@deloitte.cor< td=""><td><u>n</u>&gt;</td><td></td><td></td><td></td><td></td><td></td><td></td></ningonzalez@deloitte.cor<>	<u>n</u> >						
Cc: "Melencio, Cheryl (FNII	H) [T]" [¯	b	6	"  "Wood, Gretch	en (NIH/	OD) [E]"	
b6	1						

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Regards,

David

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Senior Vice-President, Research Partnerships
<u>Foundation for</u> the National Institutes of Health

b6

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Anderson, James (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=73143D1860BC42458BE254CA21573B23-ANDERSONJM]

Sent: 5/13/2020 11:23:17 AM

To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Colvis, Christine (NIH/NCATS)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Wholley, David (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH)

[T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]

Subject: FW: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time

Attachments: Need for NHP planning coordination process 5-12-2020.docx

Larry,

My responsibilities start earlier today that I thought. Attach is a summary of where we are with planning for NHP use for COVID research. Feel free to paraphrase at today's Exec Comm meeting and tomorrow's ICD meeting.

We plan to make the admin supplements to the NPRCs b5 require that the NPRCs develop a coordinating center to interact with ACTIV. Interaction with the NIAID resources still requires coordination.

Thanks for your help.

Jim

From: Wholley, David (FNIH) [7	] <b>b6</b>			
<b>Sent:</b> Tuesday, May 12, 2020 9				
To: Collins, Francis (NIH/OD) [E	] b6	; Dolsten, Mikael	b6	; Fauci, Anthony
(NIH/NIAID) [E] <b>b6</b>	Gibbons, Gar	y (NIH/NHLBI) [E]	b6	, Pao, William
	offels, Paul [JJCUS]			
b6	; Colvis, Christine (NII	H/NCATS) [E] {	b6	Desrosiers, Betsy
b6	>; Hughes, Eric	b6	; Jansen, Kathr	in
b6	Kurilla, Michael (NIH/N	CATS) [E]	b6 ; Lo\	wy, Douglas (NIH/NCI) [E]
<b>b6</b> ∤; Read, S	Sarah (NIH/NIAID) [E]	b6	Young, John	
	Menetski, Joseph (FNII			
	aren (FNIH) [T]			
Freire, Maria (FNIH) [T]	<b>b6</b> Tabak, La	wrence (NIH/OD) [E]	b6	; Lane, Cliff
(NIH/NIAID) [E] b6	; Parker, Ashley	' (NIH/OD) [E]	b6 ;	Anderson, James
(NIH/NIAID) [E] b6 (NIH/OD) [E] b6	; Austin, Ch	ristopher (NIH/NCATS	S) [E] <b>b6</b>	; Wolf-Rodda,
Julie (FNIH) [T] b6	Gonzalez, Nir	na <ningonzalez@delo< td=""><td>oitte.com&gt;</td><td></td></ningonzalez@delo<>	oitte.com>	
Cc: Melencio, Cheryl (FNIH) [T]	b6	] Wood, Gretchen (NI	IH/OD) [E] -	b6
Subject: Agenda for ACTIV EC r	neeting tomorrow mor	ning at 8:00 AM Easte	ern US Time	

Importance: High

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the agenda for our meeting tomorrow morning (via Zoom) and a copy of the letter from the Therapeutics- Clinical Working Group you received earlier today, for our discussion.

Please let Joe Menetski or Cheryl Melencio know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

fnih.org

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From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]

**Sent**: 5/13/2020 11:53:26 AM

To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; NIH Director's Executive

Committee [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8dd6ae9e97864c7a930aa2a27dc4cb28-OD-Small St]

CC: Prince, Scott (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd557b0e1194e36bc407110cb681025-princes]; OCPLPressTeam

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=53ba510dfce44512b4a76db41c90df84-OCPL Press]; Kolberg, Rebecca

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolbergr]; Pelis, Kim (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=d27af8a8b53f4728a25e9b83984ce9f1-pelisk]; George, Jill (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Kuska, Bob (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=d9c3f44321bf44ada7bdf6ac1edcfa85-kuskar]

Subject: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine

## Science



AP Photo/Ted S. Warren

# Unveiling 'Warp Speed,' the White House's Americafirst push for a coronavirus vaccine

By Jon Cohen May. 12, 2020, 5:05 PM

Science's COVID-19 reporting is supported by the Pulitzer Center.

Conventional wisdom is that a vaccine for COVID-19 is at least 1 year away, but the organizers of a U.S. government push called Operation Warp Speed have little use for conventional wisdom. The project, vaguely described to date but likely to be formally announced by the White House in the coming days, will pick a diverse set of vaccine candidates and

pour essentially limitless resources into unprecedented comparative studies in animals, fast-tracked human trials, and manufacturing. Eschewing international cooperation—and any vaccine candidates from China—it hopes to have 300 million doses by January 2021 of a proven product, reserved for Americans.

Those and other details, spelled out for *Science* by a government official involved with Warp Speed, have unsettled some vaccine scientists and public health experts. They're skeptical about the timeline and hope Warp Speed will complement, rather than compete with, ongoing COVID-19 vaccine efforts, including one announced last month by the National Institutes of Health (NIH). "Duplication only leads to infighting and slowing people down," says Nicole Lurie, former U.S. assistant secretary for preparedness and response, who advises the Coalition for Epidemic Preparedness Innovations (CEPI), a nonprofit funding and helping coordinate COVID-19 vaccine efforts. "The U.S., and others around the world, should be engaged in this competition against the virus, not against one another.

Warp Speed, first revealed by Bloomberg News on 29 April, has so far only been outlined. President Donald Trump briefly discussed the initiative the next day, saying, "We're going to fast track it like you've never seen before." According to a CNN report on 1 May, which the source who spoke to *Science* confirmed, Warp Speed intends to deliver the first 100 million doses of a vaccine in November and another 200 million over the following 2 months.

An extraordinary 110 COVID-19 vaccines are in development, and eight candidates—four from Chinese companies—have entered small trials in people, according to an 11 May update from the World Health Organization (WHO). But there's less than meets the eye in many of the efforts, says a vaccine veteran who asked not to be named. "Half of them are companies that have three guys, an administrative assistant, and a dog."

The idea for Warp Speed was hatched in early April, says the official, a scientist, who was given permission to discuss it with *Science* if his name was not used. "Looking around, it became clear that without a really heroic effort, none of the existing efforts to produce vaccine was going to lead us to have vaccine to prevent what looks increasingly like a second wave that could sweep come October, November," he says. Warp Speed will have three separate "virtual teams" to address development, supply and manufacturing, and distribution, led by a "core team" of a few dozen experts from government, industry, and academia.

Warp Speed has already narrowed its list of vaccine candidates to 14 and plans to push ahead with eight, the official says. "The idea for us is to pick a diversified portfolio" of vaccines made with different technologies, or platforms. Organizers were concerned that other government vaccine investment has been "heavily weighted" toward just two candidates: one made with messenger RNA encoding the coronavirus surface "spike" protein and the other using a cold-causing adenovirus to deliver the same protein's gene. Neither technology, the official notes, has yet led to approved vaccines for any disease.

The official declined to identify Warp Speed's vaccine candidates, but he stressed two key criteria: safety and the potential to make hundreds of millions of doses quickly. "We don't have time to debug manufacturing issues here," he says. By July, Warp Speed hopes to have its eight lead candidates in human trials. At the same time, it will fund a large-scale comparison of their safety and efficacy in hamsters and monkeys to help winnow down that group. "If something's really bad, we'll get rid of it," he says.

In parallel with the trials, the project will lay the groundwork for "heavy duty manufacturing" of as many as four different vaccines. More than one may prove worthy, and multiple options guard against contamination incidents and other supply concerns.

Although Warp Speed has not ruled out any type of vaccine, it will not consider ones made in China, such as the inactivated virus vaccine recently shown to protect monkeys from the coronavirus, a first. "We can't partner with Chinese companies," the official says. "That's just not going to happen." The decision was "above my pay grade," he adds. But the chosen vaccines could be made by a company that is not headquartered in the United States. (White House trade adviser Peter Navarro in a February memo to the Coronavirus Task Force championed a "Manhattan Project" for COVID-19 vaccines that would prioritize U.S.-based companies.)

Warp Speed's main goal is to protect the United States. "The attitude here is the oxygen mask approach," the official says. "We want to get our oxygen mask on first and then we're going to help the people around us." Warp Speed, he says, plans to "freely disseminate information" to other countries and share manufacturing technologies, and it may make extra doses for the world.

Many scientists and organizations have argued, however, that any proven COVID-19 vaccines should be accessible and affordable to everyone in the world at the same time. WHO and other groups on 24 April formed the Access to COVID-19 Tools Accelerator that aims to speed development of diagnostics, therapeutics, and vaccines, and ensure "equitable global access to safe, quality, effective, and affordable" products. The European Commission, in turn, organized a fundraiser on 4 May, the Coronavirus Global Response, at which world leaders from many countries and some philanthropists pledged \$8 billion; the United States did not participate. CEPI and another nonprofit group, GAVI, the Vaccine Alliance, will oversee the vaccine drive. "It's a global problem, and it needs a global solution," says Seth Berkley, who heads GAVI.

Berkley supports Warp Speed's plan to triage the many candidates, but he calls it a shortsighted mistake to rule out Chinese products, "given the fact that they're a couple of months ahead." The Bill & Melinda Gates Foundation is closely following "15 or so" vaccine candidates, including ones from China, and will support the most promising ones, adds Emilio Emini, a former vaccine developer now with the foundation. "You need to have a global portfolio so that you're not putting all your chips on one part of the roulette table," he says.

WHO has yet another ambitious COVID-19 vaccine project, the <u>Solidarity Trial</u>, that plans to compare candidates in human studies. That effort is headed by Andrew Witty, former CEO of GlaxoSmithKline, a major vaccine manufacturer. On Monday, WHO Director-General Tedros Adhanom Ghebreyesus said <u>there are seven or eight "top" vaccine candidates</u> the group hopes to accelerate. What will happen with production and supply if one of these other groups and Warp Speed select the same vaccine to prioritize is unknown.

Warp Speed's relationship to the NIH initiative, Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), remains unclear. That project plans to coordinate clinical trials of several COVID-19 vaccines and use common institutional review boards, safety monitors, and protocols, NIH Director Francis Collins and co-authors explain in a commentary published online on 11 May by *Science*. ACTIV is also considering controversial human "challenge" studies, which would fast-track a vaccine's evaluation by immunizing healthy people and deliberately infecting them with the new coronavirus or a weakened form of it.

When asked about the NIH effort, the Warp Speed official said there is "no conflict at all—they are working together—one intellectually (ACTIV) and one operationally (Warp Speed)." But several scientists on the ACTIV vaccine subcommittee say they know little about Warp Speed. And one member, Peter Hotez of the Baylor College of Medicine, worries about both its name and timeline, noting the antivaccine movement argues products are often rushed to market without adequate testing. "Some of the language coming out of the White House is very damaging," says Hotez, who is part of a team making a COVID-19 vaccine candidate. As for the January delivery of 300 million doses, "I don't see a path by which you can collect enough efficacy and safety data by the end of the year."

Kathryn Edwards, a vaccine specialist at Vanderbilt University who is also participating in ACTIV, notes that the efficacy trials, which will ideally track symptomatic disease in areas of high transmission, also face complicated logistical issues given that many people will only have mild cases of COVID-19 or not know they are infected at all.

The official acknowledges Warp Speed is aiming high. "I know that there's a reasonable probability that we're going to fail," he says. "And if we fail, I want to make sure we've investigated all of the different potential ways we could have gone."

### Posted in:

- Health
- Coronavirus

doi:10.1126/science.abc7056

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL] Sent: 5/13/2020 1:02:28 PM To: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp] Subject: Re: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time Thanks Jim. I did speak on your behalf, emphasizing that you have connected with all primate centers and that they are onboard, but we need the exec comm guidance about priorities. Larry From: "Anderson, James (NIH/OD) [E]" b6 Date: Wednesday, May 13, 2020 at 7:25 AM To: "Tabak, Lawrence (NIH/OD) [E]" "Colvis, Christine (NIH/NCATS) [E]" "Menetski, Joseph (FNIH) [T]" "Wholley, David (FNIH) [T] **b6** Subject: FW: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time Larry, My responsibilities start earlier today that I thought. Attach is a summary of where we are with planning for NHP use for COVID research. Feel free to paraphrase at today's Exec Comm meeting and tomorrow's ICD meeting. We plan to make the admin supplements to the NPRCs ( b5 require that the NPRCs develop a coordinating center to interact with ACTIV. Interaction with the NIAID resources still requires coordination. Thanks for your help. Jim From: Wholley, David (FNIH) [T] **b6** Sent: Tuesday, May 12, 2020 9:57 PM **b6** To: Collins, Francis (NIH/OD) [E] b6 Dolsten, Mikael ; Fauci, Anthony (NIH/NIAID) [E] Gibbons, Gary (NIH/NHLBI) [E] b6 b6 b6 Stoffels, Paul [JJCUS] Woodcock, Janet (FDA/CDER) Colvis, Christine (NIH/NCATS) [E] ; Desrosiers, Betsy b6 ; Hughes, Eric 🗄 Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] h6 Lowy, Douglas (NIH/NCI) [E] Read, Sarah (NIH/NIAID) [E] Young, John b6 ; Menetski, Joseph (FNIH) [T] b6 b₆ ; Adam, Stacey (FNIH) [T] ;; Tountas, Karen (FNIH)[T] 🗄 Santos, Michael (FNIH) [T] Tabak, Lawrence (NIH/OD) [E] Freire, Maria (FNIH) [T] ; Lane, Cliff (NIH/NIAID) [E] Parker, Ashley (NIH/OD) [E][ b6 Anderson, James ; Austin, Christopher (NIH/NCATS) [E] (NIH/OD) [E] Wolf-Rodda, Julie (FNIH) [T] Gonzalez, Nina

Cc: Melencio, Cheryl (FNIH) [T]	b6	; Wood, Gretchen (NIH/OD) [E]	b6
		morning at 8:00 AM Eastern US Time	
Dear ACTIV EC members, Working G Please see attached the agenda for Therapeutics- Clinical Working Grou	our meeting t	tomorrow morning (via Zoom) and a copy	of the letter from the
Please let Joe Menetski or Cheryl Me productive meeting.	elencio know	if you are having any problems connectin	g. I look forward to a
Regards,			
David			
David Wholley			
Senior Vice-President, Research P	artnerships		
Foundation for the National Instit	utes of Healt	ħ	
b6			
<u>fnih.org</u>			
11400 Rockville Pike Suite 600 Nor	th Bethesda, l	MD 20852	

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]

**Sent**: 5/13/2020 3:09:36 PM

CC:

To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Burklow, John (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj] Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wolinetz, Carrie (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Wholley, David (FNIH)

[T] [/o=ExchangeLabs/ou=Exchange Administrative Group

Kuska, Bob (NIH/OD) [E]

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

It's really unfortunate that Jon Cohen is painting a picture of some kind of conflict or duplication between

Subject: FW: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine

ACTIV and Operation Warp Speed. That's not the case at all. He also says that ACTIV is considering human challenge trials, which is absolutely not the case. How come Jon didn't reach out to me? b5 Francis From: Myles, Renate (NIH/OD) [E] Sent: Wednesday, May 13, 2020 7:53 AM b6 ; NIH Director's Executive Committee < OD-To: Collins, Francis (NIH/OD) [E] SmallStaff@mail.nih.gov> Cc: Prince, Scott (NIH/OD) [E] ;; OCPLPressTeam < OCPLPressTeam@od.nih.gov >; Kolberg, Pelis, Kim (NIH/OD) [E] Rebecca (NIH/OD) [E] b6 b6 ; George, Jill (NIH/OD) [E]

b6

Subject: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine

## Science



AP Photo/Ted S. Warren

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- Coronavirus

doi:10.1126/science.abc7056

From:	Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent:	5/13/2020 3:17:47 PM
То:	Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
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Subject:	RE: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine
about ACTI	out to him about the human challenge studies and asked him to correct it. He did not reach out to talk to us V, but it appears he spoke to plenty of the WG members.  up a call with Jon so you can talk through it with him (without giving away too much). Thoughts?
From: Colli	ns, Francis (NIH/OD) [E] <b>b6</b>
Sent: Wedr	nesday, May 13, 2020 11:10 AM  Renate (NIH/OD) [E]
To: Myles,	Renate (NIH/OD) [E] [ D6 ; Burklow, John (NIH/OD) [E] [ D6 ]
CC: Tabak, I	Lawrence (NIH/OD) [E] <b>b6</b> Wolinetz, Carrie (NIH/OD) [E] <b>b6</b> avid (FNIH) [T] <b>b6</b>
	V: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine
ACTIV and challenge	unfortunate that Jon Cohen is painting a picture of some kind of conflict or duplication between Operation Warp Speed. That's not the case at all. He also says that ACTIV is considering human trials, which is absolutely not the case. How come Jon didn't reach out to me?    b5
From: Myle	es, Renate (NIH/OD) [E] <b>b6</b>
	nesday, May 13, 2020 7:53 AM
	Francis (NIH/OD) [E] <b>b6</b> ; NIH Director's Executive Committee < <u>OD-</u> Dimail.nih.gov>

Subject: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine

; Kuska, Bob (NIH/OD) [E]

Pelis, Kim (NIH/OD) [E]

OCPLPressTeam < OCPLPressTeam@od.nih.gov>; Kolberg,

; George, Jill (NIH/OD) [E]

b6

## Science

Cc: Prince, Scott (NIH/OD) [E]
Rebecca (NIH/OD) [E]



AP Photo/Ted S. Warren

# Unveiling 'Warp Speed,' the White House's Americafirst push for a coronavirus vaccine

By Jon Cohen May. 12, 2020, 5:05 PM

Science's COVID-19 reporting is supported by the Pulitzer Center.

Conventional wisdom is that a vaccine for COVID-19 is at least 1 year away, but the organizers of a U.S. government push called Operation Warp Speed have little use for conventional wisdom. The project, vaguely described to date but likely to be formally announced by the White House in the coming days, will pick a diverse set of vaccine candidates and pour essentially limitless resources into unprecedented comparative studies in animals, fast-tracked human trials, and manufacturing. Eschewing international cooperation—and any vaccine candidates from China—it hopes to have 300 million doses by January 2021 of a proven product, reserved for Americans.

Those and other details, spelled out for *Science* by a government official involved with Warp Speed, have unsettled some vaccine scientists and public health experts. They're skeptical about the timeline and hope Warp Speed will complement, rather than compete with, ongoing COVID-19 vaccine efforts, including one announced last month by the National Institutes of Health (NIH). "Duplication only leads to infighting and slowing people down," says Nicole Lurie, former U.S. assistant secretary for preparedness and response, who advises the Coalition for Epidemic Preparedness Innovations (CEPI), a nonprofit funding and helping coordinate COVID-19 vaccine efforts. "The U.S., and others around the world, should be engaged in this competition against the virus, not against one another.

Warp Speed, first revealed by Bloomberg News on 29 April, has so far only been outlined. President Donald Trump briefly discussed the initiative the next day, saying, "We're going to fast track it like you've never seen before." According to a CNN report on 1 May, which the source who spoke to *Science* confirmed, Warp Speed intends to deliver the first 100 million doses of a vaccine in November and another 200 million over the following 2 months.

An extraordinary 110 COVID-19 vaccines are in development, and eight candidates—four from Chinese companies—have entered small trials in people, according to an 11 May update from the World Health Organization (WHO). But there's less than meets the eye in many of the efforts, says a vaccine veteran who asked not to be named. "Half of them are companies that have three guys, an administrative assistant, and a dog."

The idea for Warp Speed was hatched in early April, says the official, a scientist, who was given permission to discuss it with *Science* if his name was not used. "Looking around, it became clear that without a really heroic effort, none of the

existing efforts to produce vaccine was going to lead us to have vaccine to prevent what looks increasingly like a second wave that could sweep come October, November," he says. Warp Speed will have three separate "virtual teams" to address development, supply and manufacturing, and distribution, led by a "core team" of a few dozen experts from government, industry, and academia.

Warp Speed has already narrowed its list of vaccine candidates to 14 and plans to push ahead with eight, the official says. "The idea for us is to pick a diversified portfolio" of vaccines made with different technologies, or platforms. Organizers were concerned that other government vaccine investment has been "heavily weighted" toward just two candidates: one made with messenger RNA encoding the coronavirus surface "spike" protein and the other using a cold-causing adenovirus to deliver the same protein's gene. Neither technology, the official notes, has yet led to approved vaccines for any disease.

The official declined to identify Warp Speed's vaccine candidates, but he stressed two key criteria: safety and the potential to make hundreds of millions of doses quickly. "We don't have time to debug manufacturing issues here," he says. By July, Warp Speed hopes to have its eight lead candidates in human trials. At the same time, it will fund a large-scale comparison of their safety and efficacy in hamsters and monkeys to help winnow down that group. "If something's really bad, we'll get rid of it," he says.

In parallel with the trials, the project will lay the groundwork for "heavy duty manufacturing" of as many as four different vaccines. More than one may prove worthy, and multiple options guard against contamination incidents and other supply concerns.

Although Warp Speed has not ruled out any type of vaccine, it will not consider ones made in China, such as the inactivated virus vaccine recently shown to protect monkeys from the coronavirus, a first. "We can't partner with Chinese companies," the official says. "That's just not going to happen." The decision was "above my pay grade," he adds. But the chosen vaccines could be made by a company that is not headquartered in the United States. (White House trade adviser Peter Navarro in a February memo to the Coronavirus Task Force championed a "Manhattan Project" for COVID-19 vaccines that would prioritize U.S.-based companies.)

Warp Speed's main goal is to protect the United States. "The attitude here is the oxygen mask approach," the official says. "We want to get our oxygen mask on first and then we're going to help the people around us." Warp Speed, he says, plans to "freely disseminate information" to other countries and share manufacturing technologies, and it may make extra doses for the world.

Many scientists and organizations have argued, however, that any proven COVID-19 vaccines should be accessible and affordable to everyone in the world at the same time. WHO and other groups on 24 April formed the Access to COVID-19 Tools Accelerator that aims to speed development of diagnostics, therapeutics, and vaccines, and ensure "equitable global access to safe, quality, effective, and affordable" products. The European Commission, in turn, organized a fundraiser on 4 May, the Coronavirus Global Response, at which world leaders from many countries and some philanthropists pledged \$8 billion; the United States did not participate. CEPI and another nonprofit group, GAVI, the Vaccine Alliance, will oversee the vaccine drive. "It's a global problem, and it needs a global solution," says Seth Berkley, who heads GAVI.

Berkley supports Warp Speed's plan to triage the many candidates, but he calls it a shortsighted mistake to rule out Chinese products, "given the fact that they're a couple of months ahead." The Bill & Melinda Gates Foundation is closely following "15 or so" vaccine candidates, including ones from China, and will support the most promising ones, adds Emilio Emini, a former vaccine developer now with the foundation. "You need to have a global portfolio so that you're not putting all your chips on one part of the roulette table," he says.

WHO has yet another ambitious COVID-19 vaccine project, the <u>Solidarity Trial</u>, that plans to compare candidates in human studies. That effort is headed by Andrew Witty, former CEO of GlaxoSmithKline, a major vaccine manufacturer. On Monday, WHO Director-General Tedros Adhanom Ghebreyesus said <u>there are seven or eight "top" vaccine</u>

<u>candidates</u> the group hopes to accelerate. What will happen with production and supply if one of these other groups and Warp Speed select the same vaccine to prioritize is unknown.

Warp Speed's relationship to the NIH initiative, Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), remains unclear. That project plans to coordinate clinical trials of several COVID-19 vaccines and use common institutional review boards, safety monitors, and protocols, NIH Director Francis Collins and co-authors explain in a commentary published online on 11 May by *Science*. ACTIV is also considering controversial human "challenge" studies, which would fast-track a vaccine's evaluation by immunizing healthy people and deliberately infecting them with the new coronavirus or a weakened form of it.

When asked about the NIH effort, the Warp Speed official said there is "no conflict at all—they are working together—one intellectually (ACTIV) and one operationally (Warp Speed)." But several scientists on the ACTIV vaccine subcommittee say they know little about Warp Speed. And one member, Peter Hotez of the Baylor College of Medicine, worries about both its name and timeline, noting the antivaccine movement argues products are often rushed to market without adequate testing. "Some of the language coming out of the White House is very damaging," says Hotez, who is part of a team making a COVID-19 vaccine candidate. As for the January delivery of 300 million doses, "I don't see a path by which you can collect enough efficacy and safety data by the end of the year."

Kathryn Edwards, a vaccine specialist at Vanderbilt University who is also participating in ACTIV, notes that the efficacy trials, which will ideally track symptomatic disease in areas of high transmission, also face complicated logistical issues given that many people will only have mild cases of COVID-19 or not know they are infected at all.

The official acknowledges Warp Speed is aiming high. "I know that there's a reasonable probability that we're going to fail," he says. "And if we fail, I want to make sure we've investigated all of the different potential ways we could have gone."

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	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject:	RE: Science: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine
We also nee	ed to have a crisp answer about the relationship between ACTIV and Operation Warp Speed. And
	s the Manhattan Project 2. People are getting confused.
then there s	, the Maintattan Poject 2. People are getting confused.
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	sdav. Mav 13. 2020 11:18 AM
	rancis (NIH/OD) [E] b6 Burklow, John (NIH/OD) [E] b6
Cc: Tabak, La	wrence (NIH/OD) [E] <b>b6</b> ; Wolinetz, Carrie (NIH/OD) [E] <b>b6</b> ;
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	s, Francis (NIH/OD) [E] <b>b6</b>
	sday, May 13, 2020 11:10 AM
	enate (NIH/OD) [E] <b>b6</b> Burklow, John (NIH/OD) [E] <b>b6</b>
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	rancis (NIH/OD) [E] <u>b6</u> NIH Director's Executive Committee < <u>OD</u>
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<b>b6</b> <b>Subject:</b> Scie	b6 ; Kuska, Bob (NIH/OD) [E] b6 nce: Unveiling 'Warp Speed,' the White House's America-first push for a coronavirus vaccine

## Science



AP Photo/Ted S. Warren

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/14/2020 12:12:53 AM Sent: To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, ; Eisner, Mark b6 } Gottesdiener, Keith Hughes, Eric b6 Judy Currier Ruxandra b6 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa b6 Levy, Elliot b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish | b6 | Peppercorn, Amanda | b6 | Poole, Mike | b6 | Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy ; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey) CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy

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 } Butcher, Tina
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 ; Macone, Erin
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];
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	Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas
	Smalldon   b6 ; Stratton, Benjamin [bstratton@DELOITTE.com];
	<b>b6</b> ; Mollica, Linda /US <b>b6</b> ; Qashu, Felicia (NIH/OD) [E]
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Subject:	Materials for ACTIV TX-Clinical Working Group #6
Attachments:	FDA Guidance on COVID Trials.pdf; ACTIV Therapeutics-Clinical Full Working Group_14May2020 Meeting Guide.pdf
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Dear TX-Clinio	cal Working Group,
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	ttached the slides for tomorrow's call to help facilitate our report outs from both groups. If you have any
additions or a	amendments to propose, please send them to me.
The se shairs	will be underling the group on the ACTIV Evecutive Committee's feedback and promised actions in
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Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/14/2020 12:13:17 AM Sent: To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, b6 | Eisner, Mark | b6 | Gottesdiener, Keith | j. Hughes, Eric | b6 | j. Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa b6 Levy, Elliot b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep b6; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; **b6** Peppercorn, Amanda **b6** Patel, Naimish ; Poole, Mike Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn ]; Garner, Carl b6 Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy ; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy

b6 Jansen, Kathrin b6 ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group 
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 Melencio, Cheryl (FNIH) [T]
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	[jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];
	Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio b6 Rose
	Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas
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Subject:	ACTIV TX-Clinical Working Group #6
Attachments:	FDA Guidance on COVID Trials.pdf; ACTIV Therapeutics-Clinical Full Working Group_14May2020 Meeting Guide.pdf
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Start:	5/14/2020 6:00:00 PM
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Required	Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner,
Attendees:	Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John;
	Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael,
	Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH)
	[T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs,
	Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E];
	Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]
Optional	Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas
Attendees:	(NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla;
	Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman,
	Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon;
	Stratton, Benjamin; b6 Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy
	(NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] b6
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Dear TX-Clinical Working Group,

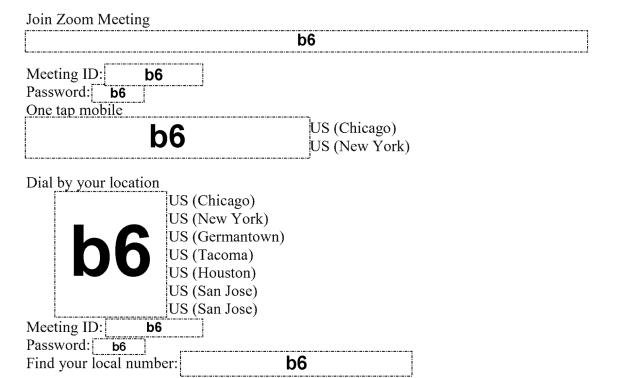
Please find attached the slides for tomorrow's call to help facilitate our report outs from both groups. If you have any additions or amendments to propose, please send them to me.

The co-chairs will be updating the group on the ACTIV Executive Committee's feedback and promised actions in response to our letter. This will include some immediate next steps for our group on the mAbs master protocol discussion. Thank you all once again for this feedback to the leadership. It was well received, and it looks like will elicit immediate action on some of the requests.

In addition, please find attached the FDA Guidance for COVID-19 trials that was released today. You can also find it at this link if needed: <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-developing-drugs-and-biological-products-treatment-or-prevention">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-developing-drugs-and-biological-products-treatment-or-prevention</a>

Looking forward to tomorrow's call.

Thanks, Stacey



From:	Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
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	b6 ; Wachtel, Jonathan [jwachtel@deloitte.com]; Weinmann, Gail (NIH/NHLBI) [E]
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CC:	Criffield, Robin b6 ; Hamilton, Nancy b6 ; Melencio, Cheryl
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	(NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	<b>b6</b> ; Jansen, Kathrin <b>b6</b> ; Lowy, Douglas (NCI)
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	Heaton, Penny b6 James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
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	Rose b6 Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative

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Subject: Summary and action items - CT Capacity WG meeting #8

Attachments: Clinical_Trial_Capacity_Working_Group_Meeting 8_Summary_Final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #8 (May 12, 2020) of the full working group. The next full working group meeting is scheduled for Friday, May 15 at 9 am eastern time USA. Looking forward to it!

Kind regards, Karen

### Karen H. Tountas, PhD Scientific Program Manager

Foundation for the National Institutes of Health

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Sent:	5/14/2020 1:41:36 AM
го:	Eric Hughes <b>b6</b> ; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa];
	Ruxandra Draghia-Akli <b>b6</b> ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel <b>b6</b> ; Colvis,
	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John
	b6 ]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike
	Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];
	Vincent, Michael b6; Keith Gottesdiener b6; Elliott Levy
	b6 ; Wung, Peter /US b6 ; Koroshetz, Walter (NIH/NINDS) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner
	[b6]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	Maria [rosalvarez@deloitte.com]; Salathin, Carla <b>b6</b>
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	b6 ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Dana Carluccio
	b6 ; Rose Li Central Account [FNIH@roseliassociates.com]
Subject:	Materials for the ACTIV TX-Clinical Agent Prioritization Subgroup #10
Attachments:	IL-6 Trial Information.pdf; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_14May2020 Meeting
	Guide.pdf; Therapeutic information request form-v4.docx

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for tomorrow's call. We will use them to follow up on our conversations from Tuesday, and well as discuss next steps.

### The materials include:

- Meeting slides for tomorrow, which have both the updated Agent Prioritization Criteria and Weighted Scoring Rubric for your review. Please take a look and see if Elizabeth and I captured all your thoughts from Tuesday.
- 2. Slides with Status of IL-6 trials for three agents in the clinic. Please take a look at these slides and see if this is the type of snapshot information you have wanted to be able to pull for any given agent as you review. While I know there is some desirable information missing, such as RCT vs. uncontrolled trial, if it looks good, feel free to play around a bit more with the tracker from Oxford that I pulled the data from: <a href="http://covid19.trialstracker.net/data_viz.html">http://covid19.trialstracker.net/data_viz.html</a>. What I am hoping to understand is if there are publicly available sites that can help fill our data aggregation needs until we can potentially get access to others that maybe more comprehensive. For comparison to the Oxford site, you can check out the Cytel site which maps the trials to given countries, but only shows intended accrual and not current accrual like the Oxford site: <a href="https://covid19-">https://covid19-</a>

- trials.com/. The challenge is likely that we may need a couple sites to fulfill the information that we need, but it would prevent us from reinventing the wheel that other maybe creating already. I will continue exploring options, but thanks for reviewing.
- 3. Finally, as discussed on Tuesday, the preclinical group and our team have worked to put together a first version of the company survey/RFI that we would use for multiple purposes: 1) to do specific information solicitation on high priority compounds that this group wishes to score, 2) to have any company or group who has submitted an agent for your consideration populate this so we are working on the right data, and 3) potentially to do a broad company solicitation of additional compounds that the companies would like to have considered for testing.

Please review and let us know if this has all the questions you would want to see to ensure that we will have the right data to review for our high priority compounds. We have worked to balance being thorough with making sure it is not too onerous for a company to fill out. Please let us know if you have any amendments or additions.

Thank you for your review of these materials. We look forward to a productive call tomorrow.

Thanks, Stacey Stacey J. Adam, PhD Director, Cancer Research Partnerships Mobile: (301) 318-8310 Direct: b6 Join Zoom Meeting b6 Meeting ID: b6 Password: b6 One tap mobile US (Chicago) **b6** US (New York) Dial by your location US (Chicago) US (New York) US (Germantown) US (Houston) US (San Jose)

b6

US (San Jose) US (Tacoma)

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Meeting ID:

Password: **b6** 

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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	5/14/2020 1:41:42 AM
Sent: To:	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/14/2020 1:41:42 AM  Fric Hughes
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Dana Carluccio b6 ]; Rose Li Central Account [FNIH@roseliassociates.com]
Subject: Attachments:	ACTIV TX-Clinical Agent Prioritization Subgroup #10  IL-6 Trial Information.pdf; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_14May2020 Meeting  Guide.pdf; Therapeutic information request form-v4.docx
Location:	b6
Start: End: Show Time As:	5/14/2020 5:00:00 PM 5/14/2020 6:00:00 PM Tentative
Required Attendees:	Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees:	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; <b>b6</b> Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] <b>b6</b> ); Dana Carluccio; Rose Li Central Account

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

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Please review and let us know if this has all the questions you would want to see to ensure that we will have the right data to review for our high priority compounds. We have worked to balance being thorough with making sure it is not too onerous for a company to fill out. Please let us know if you have any amendments or additions.

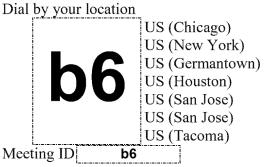
Thank you for your review of these materials. We look forward to a productive call tomorrow.

Thanks,
Stacey

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| Meeting ID: | b6 |
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Password: **b6**Find your local number **b6** 

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]

**Sent**: 5/14/2020 2:10:25 AM

To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)

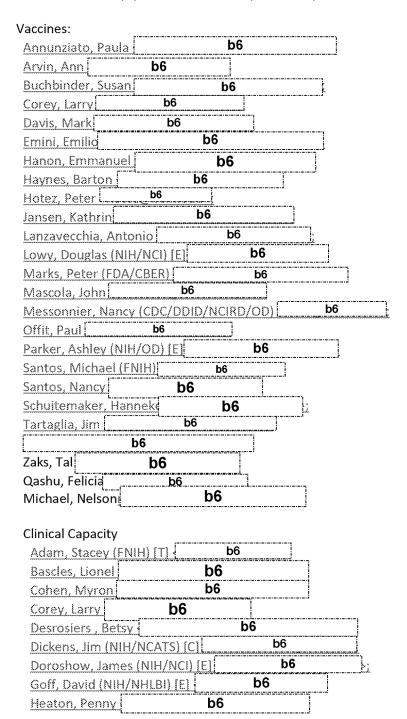
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

**Subject**: RE: JAMA Viewpoint on ACTIV: please review

Attachments: Master and WG Email List for ACTIV rv 05042020_cm.xlsx

Here is what Cheryl provided as of Friday – she may have additional updates.



Kurilla, Mike	b6 :	
Nayak, Seema (NIH/I	JIAID) [F]	b6
Parker, Ashley (NIH/		b6
Payton, Manzine	<u> </u>	<u>Do</u>
Resnansky, Laura	b6	
Srinivasan, Badhri		06
Stein, Peter (FDA/CD		b6
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Vincent, Mike	<u></u>	<u> </u>
Wachtel, Jonatha	b6	
Woodcock, Janet (FD	i	
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Qashu, Felicia <felicia< th=""><th></th><th>! ov&gt;</th></felicia<>		! ov>
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Adams, Peter (OS/AS	PR/BARDA)	b6
Alvarez, Rosa <rosalv< th=""><th>/arez@deloitte.</th><th>com&gt;;</th></rosalv<>	/arez@deloitte.	com>;
Anderson, Annaliesa	F	b6
Baric, Ralph	b6	
Carter, Kara	b6	
Colvis, Christine	b6	
Deming, Damon (FD/	A/CDER)	b6
Diamond, Michael	b6	
Duncan, Ken	b6	<u></u>
Fernandes, Prabhava	ithi {	b6
	o6	i
Grobler, Jay	b6	
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Menetski, Joseph (FN Nestle, Frank Ottinger, Liz Parker, Ashley (NIH/O Payne, David Rao, Srinivas Rappaport, Jay Stegmeier, Frank Young, John	b6 b6 DD) [E] b6 b6 b6 b6 b6	
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Buchman, Tim (OS/A	CDD/DAD	DA) (CTR	١	b6	•			
Butterton, Joan	JENY DAN	b6	4		ê.			
Currier, Judy	L.C		<u> </u>					
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De Claro, R. Angelo (			b6	j				
Draghia-Akli, Ruxano		b6	i					
Eisner, Mark	b6		<u></u>					
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Parker, Ashley (NIH/	<u> </u>		b6					
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Shen, Yuan Li (FDA/C			b6	]				
Stein, Peter (FDA/CD		b						
Higgs, Elizabeth		6		!				
Koroshetz, Walter		b6	i					
Farley, John	b6							
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<b>rom:</b> Wholley, David	(FNIH) [T	]	b6					
<b>ent:</b> Wednesday, Ma	ıy 13, 202	20 10:04 F	PM					
<b>o:</b> Melencio, Cheryl (			h6					
Cc: Parker, Ashley (NI		L	b6					
ubject: FW: JAMA Vi	ewpoint (	on ACTIV	: please rev	ew				
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ent: Wednesday, Ma o: Myles, Renate (NI	y 13, 202 H/OD) [E	][	b6	, Parker, As	hley (NIH/OD) [E	-] [		Kolb
From: Collins, Francis Fent: Wednesday, Ma Fo: Myles, Renate (NI Rebecca (NIH/OD) [E]	ay 13, 202 H/OD) [E	b6				γ		Kolb
<b>Sent:</b> Wednesday, Ma To: Myles, Renate (NI Rebecca (NIH/OD) [E] Cc: Burklow, John (NII	ny 13, 202 H/OD) [E H/OD) [E]	<b>b6</b>	b6	Tabak, Lav	vrence (NIH/OD)	) [E] [	b6	
ent: Wednesday, Ma o: Myles, Renate (NI ebecca (NIH/OD) [E]	ny 13, 202 H/OD) [E H/OD) [E]	b6	b6		vrence (NIH/OD)	γ	b6	Kolb r, Ashley

I'm glad to send the query if someone will draft the message and someone else (Cheryl?) will send me the list of e-mails for all of the WG members. From: Myles, Renate (NIH/OD) [E] Sent: Wednesday, May 13, 2020 6:12 PM Parker, Ashley (NIH/OD) [E] b6 To: Collins, Francis (NIH/OD) [E] Kolberg, b6 Rebecca (NIH/OD) [E] b6 Cc: Burklow, John (NIH/OD) [E] Tabak, Lawrence (NIH/OD) [E] b6 b6 Wholley, David (FNIH) [T] b₆ Subject: RE: JAMA Viewpoint on ACTIV: please review No surprise there. We need to get permission from the EC/WG members quickly. What's the best way to do this? Renate Myles, MBA Deputy Director for Public Affairs Office of Communications and Public Liaison National Institutes of Health From: Collins, Francis (NIH/OD) [E] Sent: Wednesday, May 13, 2020 5:48 PM To: Parker, Ashley (NIH/OD) [E] b6 Kolberg, Rebecca (NIH/OD) [E] b6 Burklow, John (NIH/OD) [E] { Cc: Myles, Renate (NIH/OD) [E] Tabak, Wholley, David (FNIH) [T] Lawrence (NIH/OD) [E] b6 Subject: FW: JAMA Viewpoint on ACTIV: please review Hey Ashley and Rebecca, Can you give these galley proofs a very close read, and let me know if you find anything amiss? Renate, note that they are asking for the ACTIV website URL. Very timely, I'd say! Francis From: Stacy Christiansen **b6** Sent: Wednesday, May 13, 2020 5:22 PM To: Collins, Francis (NIH/OD) [E] Cc: Howard Bauchner , Karen Bucher Subject: JAMA Viewpoint on ACTIV: please review Dear Dr Collins. Attached please find a proof of your Viewpoint for JAMA on the ACTIV initiative. We have typeset your figure herein, and I am cc'ing the illustrator, Karen Bucher, so we can handle any text or graphics changes simultaneously. The only query to you is the completion of reference 5, the ACTIV portal URL. I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly. Thank you so much!

Best, Stacy

Stacy L. Christiansen, MA Managing Editor, *JAMA* Chair, *AMA Manual of Style* 



Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc] Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups Attachments: Master list for ACTIV 041520.xlsx The following emails were missing from the list that went out. Cheryl – attached is a revised master list (114 contacts) with names and emails which includes everyone. Disbrow, Gary (OS/ASPR/BARDA) Kim, Elizabeth <elkim@deloitte.com> Marston, Hilary (NIH/NIAID) [E] b6 Paul, Steve Payne, David b6 b6 Plump, Andy b6 Santos, Nancy Shen, Yuan Li (FDA/CDER) b6 Thanks, Ashley From: Collins, Francis (NIH/OD) [E] Sent: Wednesday, April 15, 2020 11:39 AM ; Parker, Ashley (NIH/OD) [E] To: Melencio, Cheryl (FNIH) [T] b6 b6 Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups I already sent the other list, given the time sensitivity. What has been added here that wasn't in the other one? From: Melencio, Cheryl (FNIH) [T] Sent: Wednesday, April 15, 2020 11:19 AM Collins, Francis (NIH/OD) [E] **To:** Parker, Ashley (NIH/OD) [E] b6 Subject: List -- just copy and paste in bcc. lists of April 3 plus working groups Austin, Christopher (NIH/NCATS) [E] Bright, Rick ; Collins, Francis ; Disbrow, Gary (OS/ASPR/BARDA) (NIH/OD) [E] Corey, Larry Dolsten, Mikael [ ; Erbelding, Emily (NIH/NIAID) [E] **b6** Fauci, Anthony (NIH/NIAID) [E] 🗒 Frankowski, David ; Hudson, Thomas James, Stephanie (FNIH) **b6** b₆ ; Lane, Cliff (NIH/NIAID) [E] ; Klock, Kevin (FNIH) [T] Marks, Peter (FDA/CBER) >; Marston, Hilary (NIH/NIAID) [E] ; Menetski, Joseph (FNIH) [T] >; Meeker, David Mascola, John Pangalos, Mene ; Pao, William 🔚 **b6** Paul, Stevel... "!Perlmutter, Roger >; Plump, Andy Rasi, Guido Reed, John Rouse,

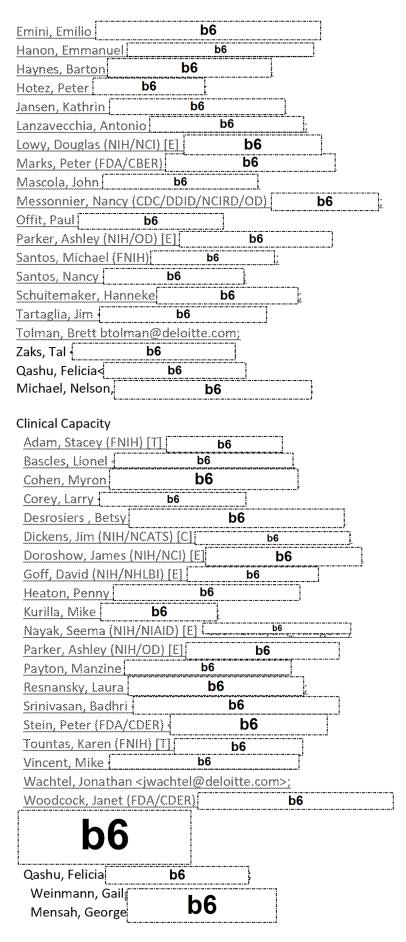
Sent:

5/14/2020 10:24:05 AM

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b6	; Vessey, Ruper	t b6	; Virgin, Sk	p	, Wholley, David
NIH) [T] <b>b</b> (	; Woodco	ck, Janet (FDA/CDER)	) <u>[</u>	06	_; Young, John
h6	Adam, Sta	cey (FNIH) [T]	<b>b6</b> ; Ba	scles, Lionel _,	
	; Cohen, M	yroni	b <b>6</b>	; Corey, Larry	b6
esrosiers , Betsy	b6	; Dicker	ns, Jim (NIH/NCA	TS) [C] [	b6 ;
oroshow, James (NII	1/NCI) [E] <	<b>b6</b> ; Gof	f, David (NIH/NF	ILBI) [E]	b6 Heaton,
enny	b <b>6</b> Kir	ng, James	<b>56</b> ; Ku	rilla, Mike	<b>b6</b> Nayak, ; Payton, Manz
eema (NIH/NIAID) [E	[ b6	Parker, Ashle	ey (NIH/OD) [E] {	b6	; Payton, Manz
b6	; Resnansky, La	eura[be Peter (FDA/CDER) {	S	rinivasan, Badhr	i
b6	, Ştein,	Peter (FDA/CDER) ﴿	b6	Toun	tas, Karen (FNIH) [T]
b6	Vincent, Mike	b6	Wachtel,	Jonathan <jwac< td=""><td>htel@deloitte.com&gt;;</td></jwac<>	htel@deloitte.com>;
oodcock, Janet (FDA	\/CDER) {	b6	Adam, Stacey (	FNIH) [T]	htel@deloitte.com>; b6 Bozzette,
am (NIH/NCATS) [E]	< b6	Buchman, Tim	(OS/ASPR/BARD	A) (CTR)	b6 ;
utterton, Joan	b6	De Claro, R. A	ngelo (FDA/CDEF	R) [	b6 ; b6 ; tesdiener, Keith
raghia-Akli, Ruxandr	a {b6	Eisner, Mark	∳ b6	; Got	tesdiener, Keith
b6	; Hughe:	s, Eric <b>b</b>	<b>6</b> ; ^j	udy Currier	
b6	Kim, Elizab	eth b6	>; LaVange	Lisa <	ъб ; Levy, Elli
b6	; Mellors, John	b6 ; Men	on, Sandeep ⟨	b6	; Parker,
shley (NIH/OD) [E]	b6	Patel, Naimish	b6	Pe	ppercorn, Amanda
b6	; Poole	, Mike	b6	; Proschar	ı, Michael
b6	Read, Sarah	b6	Santos, Micha	ael (FNIH) [T]	; Levy, Elli; Parker, ppercorn, Amanda n, Michael  b6 >; She ; Adams, Peter son, Annaliesa b6 ; Diamond, nandes, Prabhavathi ; Hewitt, Judit b6 Ottinger, Liz id b6  >; Arvin, Ann b6
ıan Li (FDA/CDER)	b6	; Stein, Peter	(FDA/CDER)	b6	; Adams, Peter
S/ASPR/BARDA)	b6	Alvarez, Rosa <re< td=""><td>salvarez@deloit</td><td>te.com&gt;; Ander</td><td>son, Annaliesa</td></re<>	salvarez@deloit	te.com>; Ander	son, Annaliesa
b6	Baric	, Ralph ∢ b€	}; Cart	er, Kara	b6
olvis, Christine	b6	Deming, Damon (FDA	V/CDER)	b6	; Diamond,
lichael	<b>b6</b> : D	uncan, Ken		Feri	nandes, Prabhavathi
b6	Gatto. (	Greg b6	Grobler, Jav	b6	: Hewitt, Judit
he >:Jor	son, Samantha (NIF	I/NCATS) [E]	b6	: Lutz. Cat <	b6
lenetski. Joseph (FN	H) [T] ₹ b6	Nestle. Fra	nk ⊲	h6	Ottinger, Liz
I. A	: Parker, Ashle	v (NIH/OD) [F]		Payne, Day	id
bb	Rappaport, Jav	/ b6	: Stegmei	er Frank <	b6
oung John	b6	: Annunziato Paula		16	
b6	;; Buchbinder, Susa	an <b>b6</b>	): C	orey, Larry	b6
avis, Mark {		mini, Emilio			anon, Emmanuel
b6	Haynes, B				b6 Jansen,
athrin {		nzavecchia, Antonio	- :	Ĺ	, Douglas (NIH/NCI) [E]
b6		A/CBER)		: Mascola, John	
		ancy (CDC/DDID/NCI			;, Paul
<b>b6</b>		NIH/OD) [E]		Santos, Nancy	•
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chuitemaker, Hannel		Tartaglia, Jim	b6		olman, Brett
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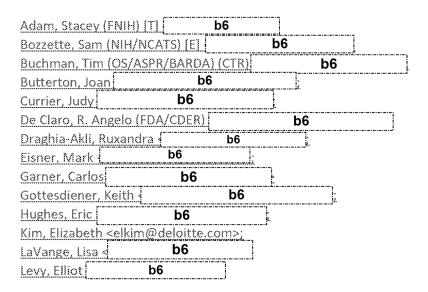
From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS] Sent: 5/14/2020 1:14:07 PM To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc] CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd] Re: JAMA Viewpoint on ACTIV: please review Subject: Hi Cheryl, I'm on a ICD call with Francis, can you please send him the list of emails? Thanks! **Ashley b6** On May 14, 2020, at 9:10 AM, Melencio, Cheryl (FNIH) [T] wrote: Hi Ashley I have added those who have been added to the working groups since Tuesday. Cheryl Cheryl Melencio Administrative Manager, Research Partnerships Foundation for the National Institutes of Health b6 fnih.org 11400 Rockville Pike Suite 600 North Bethesda, MD 20852 Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic <image002.png> From: Parker, Ashley (NIH/OD) [E] b6 Sent: Wednesday, May 13, 2020 10:10 PM To: Wholley, David (FNIH) [T] ; Melencio, Cheryl (FNIH) [T] b6 Subject: RE: JAMA Viewpoint on ACTIV: please review Here is what Cheryl provided as of Friday – she may have additional updates. Vaccines: b6 Annunziato, Paula Arvin, Ann Buchbinder, Susan b6 Corey, Larry **b6** Davis, Mark <



Preclinical

Adams, Peter (OS/	'ASPR/BARDA)		b6	
Alvarez, Rosa < ros	alvarez@deloi	itte.com>;		
Anderson, Annalie	sa[	b6		
Baric, Ralph	b6			
Carter, Kara	b6			
Colvis, Christine	b6			
Deming, Damon (F	DA/CDER)		b6	
Diamond, Michael		b6		
Duncan, Ken	b	6		
Fernandes, Prabha	ıvathi	b6	3	j
Gatto, Greg	b6			
Grobler, Jay	b6			
Hewitt, Judith	b6			
Jonson, Samantha	(NIH/NCATS)	[E]		
b6				
Lutz, Cat [	b6			,
Menetski, Joseph	(FNIH) [T]	b6		
Nestle, Frank	b6		i Ž.	
Ottinger, Liz	b6			
Parker, Ashley (Nii	H/OD) [E]	b	6	
Payne, David	b6			
Rao, Srinivas	b6	i.	_	
Rappaport, Jay	b6		<u></u>	
Stegmeier, Frank	b6	<u> </u>		
Young, John	b6			
Qashu, Felicia∢	b6			
Pitt, Louise	b6	! : :	;;	
Cihlar, Toma	b6	<u>.</u>		
essel, Josh∢	b6	<u>};</u>		
Punturieri, Tony	b6	<u>;</u>		
Charette, Mard	b6			

## Tx Clinical



Mellors, John <b>b6</b>			
Menon, Sandeep	b6		
Parker, Ashley (NIH/OD) [6	1 b6		
Patel, Naimish	b6		
Peppercorn, Amanda	b6		
Poole, Mike	<b>b6</b>		
Proschan, Michael	b6		
Read, Sarah b6			
Santos, Michael (FNIH) [T]	b6		
Shen, Yuan Li (FDA/CDER)	b6		
Stein, Peter (FDA/CDER)	b6		
Higgs, Elizabeth	b6 ;		
Koroshetz, Walter	b6		
Farley, John b	6		
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Qualitary 1 attachment	)6 		
Burgess, Timothy	j		
Reineck, Lora			
Aggarwal, Neil	b6		
Sent: Wednesday, May 13, To: Melencio, Cheryl (FNIH) Cc: Parker, Ashley (NIH/OD) Subject: FW: JAMA Viewpo	2020 10:04 PM [T] <b>b6</b> [E]		
Cc. Burklow, John (NIH/OD)	D6	Fabak, Lawrence (NIH/OD) [E]  Melencio, Cheryl (FNIH)	<b>T</b> ]
Sent: Wednesday, May 13, To: Melencio, Cheryl (FNIH) Cc: Parker, Ashley (NIH/OD) Subject: FW: JAMA Viewpo  Please help, tx  From: Collins, Francis (NIH/ Sent: Wednesday, May 13, To: Myles, Renate (NIH/OD)	D	<b>b6</b> [abak, Lawrence (NIH/OD) [E]	T]
Sent: Wednesday, May 13, To: Melencio, Cheryl (FNIH) Cc: Parker, Ashley (NIH/OD) Subject: FW: JAMA Viewpo  Please help, tx  From: Collins, Francis (NIH/ Sent: Wednesday, May 13, To: Myles, Renate (NIH/OD)	DD) [E] b6  COD) [E] b6  COD) [E] b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b6  CODO (E) b7  CODO (	b6  Tabak, Lawrence (NIH/OD) [E] b6 Melencio, Cheryl (FNIH) b6  message and someone else (Cheryl?) will	
Sent: Wednesday, May 13, To: Melencio, Cheryl (FNIH) Cc: Parker, Ashley (NIH/OD) Subject: FW: JAMA Viewpo  Please help, tx  From: Collins, Francis (NIH/ Sent: Wednesday, May 13, To: Myles, Renate (NIH/OD)	DD) [E] b6  COD) [E] b6  CODO 6:37 PM  [E] b6  Colberg, Rebecca (NIH/OD) [E] b6  Wholley, David (FNIH) [T] cer, Ashley (NIH/OD) [E] cht on ACTIV: please review	b6  Tabak, Lawrence (NIH/OD) [E] b6 Melencio, Cheryl (FNIH) b6  message and someone else (Cheryl?) will	.T]
Sent: Wednesday, May 13, To: Melencio, Cheryl (FNIH) Cc: Parker, Ashley (NIH/OD) Subject: FW: JAMA Viewpo  Please help, tx  From: Collins, Francis (NIH/Sent: Wednesday, May 13, To: Myles, Renate (NIH/OD)  b6  b6  cc: Burklow, John (NIH/OD)  b6  jc: Par  Subject: RE: JAMA Viewpoin  I'm glad to send the queresend me the list of e-mail  From: Myles, Renate (NIH/OD)  Sent: Wednesday, May 13, To: Collins, Francis (NIH/OD)	DD) [E] b6  Colberg, Rebecca (NIH/OD) [E] b6  Wholley, David (FNIH) [T] cer, Ashley (NIH/OD) [E] cht on ACTIV: please review  Wif someone will draft the s for all of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG mem	b6  Tabak, Lawrence (NIH/OD) [E]  b6  Melencio, Cheryl (FNIH)  b6  message and someone else (Cheryl?) will s.  arker, Ashley (NIH/OD) [E]	Τ]
Sent: Wednesday, May 13, To: Melencio, Cheryl (FNIH) Cc: Parker, Ashley (NIH/OD) Subject: FW: JAMA Viewpo  Please help, tx  From: Collins, Francis (NIH/Sent: Wednesday, May 13, To: Myles, Renate (NIH/OD)  b6  b6  cc: Burklow, John (NIH/OD)  b6  jc: Par  Subject: RE: JAMA Viewpoin  I'm glad to send the queresend me the list of e-mail  From: Myles, Renate (NIH/OD)  Sent: Wednesday, May 13, To: Collins, Francis (NIH/OD)	DD) [E] b6  Colberg, Rebecca (NIH/OD) [E] b6  Wholley, David (FNIH) [T] cer, Ashley (NIH/OD) [E] cht on ACTIV: please review  Wif someone will draft the s for all of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG mem	b6  Tabak, Lawrence (NIH/OD) [E]  b6  Melencio, Cheryl (FNIH)  b6  message and someone else (Cheryl?) will s.  arker, Ashley (NIH/OD) [E]	<b>T</b> ]
Sent: Wednesday, May 13, To: Melencio, Cheryl (FNIH) Cc: Parker, Ashley (NIH/OD) Subject: FW: JAMA Viewpo Please help, tx  From: Collins, Francis (NIH/Sent: Wednesday, May 13, To: Myles, Renate (NIH/OD) b6 b6 cc: Burklow, John (NIH/OD) b6 y; Par Subject: RE: JAMA Viewpoin I'm glad to send the queresend me the list of e-mail From: Myles, Renate (NIH/OD) Sent: Wednesday, May 13, To: Collins, Francis (NIH/OD) b6 y; Par Subject: RE: JAMA Viewpoin Csent: Wednesday, May 13, To: Collins, Francis (NIH/OD) b6 cc: Burklow, John (NIH/OD)	DD) [E] b6  Colberg, Rebecca (NIH/OD) [E] b6  Wholley, David (FNIH) [T] cer, Ashley (NIH/OD) [E] cht on ACTIV: please review  Wif someone will draft the s for all of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG members of the WG m	b6  Tabak, Lawrence (NIH/OD) [E] b6 Melencio, Cheryl (FNIH) b6  message and someone else (Cheryl?) will s.  arker, Ashley (NIH/OD) [E] b6 Tabak, Lawrence (NIH/OD) [E]	<u>`</u> T]
Sent: Wednesday, May 13, To: Melencio, Cheryl (FNIH) Cc: Parker, Ashley (NIH/OD) Subject: FW: JAMA Viewpo Please help, tx  From: Collins, Francis (NIH/Sent: Wednesday, May 13, To: Myles, Renate (NIH/OD) b6 b6 cc: Burklow, John (NIH/OD) b6 y; Par Subject: RE: JAMA Viewpoin I'm glad to send the queresend me the list of e-mail From: Myles, Renate (NIH/OD) Sent: Wednesday, May 13, To: Collins, Francis (NIH/OD) b6 y; Par Subject: RE: JAMA Viewpoin Csent: Wednesday, May 13, To: Collins, Francis (NIH/OD) b6 cc: Burklow, John (NIH/OD)	DD) [E] b6  Wholley, David (FNIH) [T] corporate of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG member of the WG	b6  Tabak, Lawrence (NIH/OD) [E]  b6  Melencio, Cheryl (FNIH)  b6  message and someone else (Cheryl?) will s.  arker, Ashley (NIH/OD) [E]	Τ]

No surprise there. We need to get permission from the EC/WG members quickly. What's the best way to do this? Renate Myles, MBA Deputy Director for Public Affairs Office of Communications and Public Liaison National Institutes of Health From: Collins, Francis (NIH/OD) [E] Sent: Wednesday, May 13, 2020 5:48 PM Kolberg, Rebecca (NIH/OD) [E] To: Parker, Ashley (NIH/OD) [E] b6 b6 Cc: Myles, Renate (NIH/OD) [E] ; Burklow, John (NIH/OD) [E] ; Tabak, Lawrence (NIH/OD) [E] Wholley, David (FNIH) [T] b6 Subject: FW: JAMA Viewpoint on ACTIV: please review Hey Ashley and Rebecca, Can you give these galley proofs a very close read, and let me know if you find anything amiss? Renate, note that they are asking for the ACTIV website URL. Very timely, I'd say! Francis From: Stacy Christiansen Sent: Wednesday, May 13, 2020 5:22 PM To: Collins, Francis (NIH/OD) [E] Cc: Howard Bauchner ; Karen Bucher Subject: JAMA Viewpoint on ACTIV: please review

Dear Dr Collins,

Attached please find a proof of your Viewpoint for JAMA on the ACTIV initiative. We have typeset your figure herein, and I am cc'ing the illustrator, Karen Bucher, so we can handle any text or graphics changes simultaneously.

The only query to you is the completion of reference 5, the ACTIV portal URL.

I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly.

Thank you so much! Best, Stacy Stacy L. Christiansen, MA Managing Editor, JAMA Chair, AMA Manual of Style

<image001.jpg>

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]

**Sent**: 5/14/2020 1:29:19 PM

To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Melencio, Cheryl (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: FW: JAMA Viewpoint on ACTIV: please review

# As requested by Ashley

From: Melencio, Cheryl (FNIH) [T] b6

Sent: Thursday, May 14, 2020 9:10 AM

To: Parker, Ashley (NIH/OD) [E] b6

Cc: Wholley, David (FNIH) [T] b6

Subject: RE: JAMA Viewpoint on ACTIV: please review

Hi Ashley

I have added those who have been added to the working groups since Tuesday.

# Cheryl

## Cheryl Melencio

Administrative Manager, Research Partnerships

# Foundation for the National Institutes of Health

b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

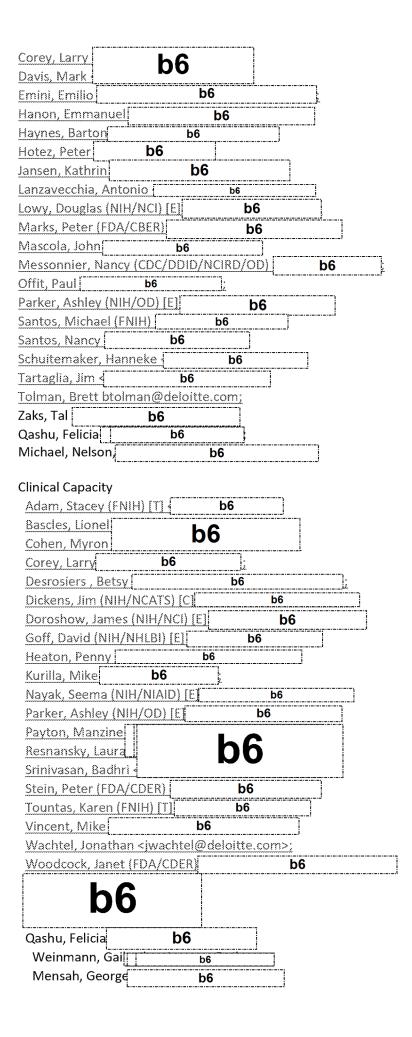


From: Parker, Ashley (NIH/OD) [E]	b	6			
Sent: Wednesday, May 13, 2020 10	):10 PM				
<b>To:</b> Wholley, David (FNIH) [T]	b6	; Melencio,	, Cheryl (FNIH) [T]	b6	
Subject: RF: JAMA Viewpoint on AC	TIV: please re	eview	i		

Here is what Cheryl provided as of Friday – she may have additional updates.

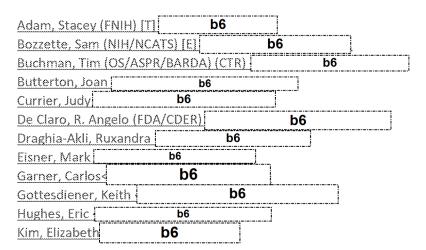
#### Vaccines:

Annunziato, Paula	b6	
Arvin, Ann <aarvin< th=""><th>b6</th><th></th></aarvin<>	b6	
Buchbinder, Susan	b6	



#### Preclinical b6 Adams, Peter (OS/ASPR/BARDA) Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Annaliesa Baric, Ralph **b6** Carter, Kara b6 Colvis, Christine Deming, Damon (FDA/CDER) b6 b6 Diamond, Michael b6 Duncan, Ken b6 Fernandes, Prabhavathi Gatto, Greg Grobler, Jay b6 Hewitt, Judith b6 Jonson, Samantha (NIH/NCATS) [E] Lutz, Cat b6 Menetski, Joseph (FNIH) [T] b6 Nestle, Frank Ottinger, Liz b6 Parker, Ashley (NIH/OD) [E] b6 Payne, David **b6** Rao, Srinivas< b6 Rappaport, Jay b6 Stegmeier, Frank Young, John b6 Qashu, Felicia b6 b6 Cihlar, Tomas b6 Fessel, Josh b6 Punturieri, Tony **b6** Charette, Marc<

# Tx Clinical

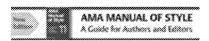


LaVange, Lisa	b6							
Levy, Elliot	b6							
Mellors, John	b6							
Menon, Sandeep		b6						
Parker, Ashley (NIH,	<u>/OD) [E]</u>	; ; ;	b6					
Patel, Naimish		b6						
Peppercorn, Amand	la		b6					
Poole, Mike		b6		]				
Proschan, Michael		b6						
Read, Sarah	b6							
Santos, Michael (FN	UH) [T][		I 0					
Shen, Yuan Li (FDA/	CDER)		<b>b</b> 6					
Stein, Peter (FDA/CI	DER) < [							
Higgs, Elizabeth		b6						
Koroshetz, Walter		b6						
Farley, John	b6		····					
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Qashu, Felicia	b6							
Burgess, Timothy		b6	j					
Reineck, Lora	b6							
Aggarwal, Nei	b	6						
From: Wholley, David	d (FNIH)	[T]	b6					
Sent: Wednesday, M		I	ł PM					
<b>To:</b> Melencio, Cheryl	(FNIH) [	T]	h6					
<b>Cc:</b> Parker, Ashley (N	IH/OD) [	[E][	b6	<u></u> j				
<b>Subject:</b> FW: JAMA V	'iewpoin	t on ACTI	V: please re	view				
Please help, tx								
<b>From:</b> Collins, Francis	-			]				
<b>Sent:</b> Wednesday, M								
To: Myles, Renate (N		[E][	b6	; Pa	rker, Ashley (N	IH/OD) [E] [	b6	Kolberg,
Rebecca (NIH/OD) [E	][	b6	L-0					
Cc: Burklow, John (N	IH/OD) [	EJ[	b6	; Ta	bak, Lawrence	(NIH/OD) [E]	D6	
Wholley, David (FNIF				lelencio,	Cheryl (FNIH) [	T] b6	; Pai	rker, Ashley
(NIH/OD) [E]				:				
Subject: RE: JAMA Vi	ewpoint	on ACTIV	r: piease rev	iew				
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I'm glad to send the				it the me	essage and so	meone eise (C	neryir) wiii s	ena me the list
of e-mails for all of	the we	nembe	ers.					
From: Myles, Renate	(NIH/O	D) [E] [	b6					
<b>Sent:</b> Wednesday, M	ay 13, 2	020 6:12	PM			<del></del>		
<b>To:</b> Collins, Francis (N			b6	; Par	ker, Ashley (NI	H/OD) [E]	b6	; Kolberg,
Rebecca (NIH/OD) [E			>					,
Cc: Burklow, John (N	IH/OD) [	E]	b6	; Ta	bak, Lawrence	(NIH/OD) [E]	b6	

Wholley, David (FNIH) [T] <b>b6</b>					
Subject: RE: JAMA Viewpoint on ACTIV: ple	ease review				
No surprise there. We need to get permiss	ion from the E	C/WG members quickly	v. What's the b	est way to do	this?
Renate Myles, MBA Deputy Director for Public Affairs Office of Communications and Public Liaiso National Institutes of Health Tel: b6	ท				
From: Collins, Francis (NIH/OD) [E]	b6				
<b>Sent:</b> Wednesday, May 13, 2020 5:48 PM		_			
To: Parker, Ashley (NIH/OD) [E]	b6	] Kolberg, Rebecca (NII	H/OD) [E]	b6	,
( , , , , , , , , , , , , , , , , , , ,	<b>b6</b>	Burklow, John (NIH/OD)	) [E] {	b6	; Tabak,
Lawrence (NIH/OD) [E] b6	Whol	ley, David (FNIH) [T]	b6	J	
Subject: FW: JAMA Viewpoint on ACTIV: pl	lease review				
Hey Ashley and Rebecca,  Can you give these galley proofs a very	close read, a	nd let me know if you	ı find anythin	ng amiss?	
Renate, note that they are asking for th	ne ACTIV web:	site URL. Very timely	, I'd say!		
From: Stacy Christiansen	b6				
Sent: Wednesday, May 13, 2020 5:22 PM					
To: Collins, Francis (NIH/OD) [E]	b6 6	y=-=-			
\		Karen Bucher		b6	
Subject: JAMA Viewpoint on ACTIV: please	review				
Dear Dr Collins, Attached please find a proof of your your figure herein, and I am cc'ing the changes simultaneously.					
The only query to you is the comple	tion of refer	ence 5, the ACTIV p	ortal URL.		
I recognize how busy you must be, I publish it quickly.	out I hope yo	ou can find time to i	review this p	proof so we	can

Thank you so much! Best, Stacy Stacy L. Christiansen, MA Managing Editor, JAMA

Chair, AMA Manual of Style



**Sent**: 5/14/2020 2:00:14 PM

Subject: ACTION: Making your ACTIV Participation Public

# Hi Francis,

I've pasted a slightly revised draft email OCPL provided to ask the ACTIV EC and WG members permission to list their names on the website. Renate – there are a few new members working group members, we can work together to update the list.

То:		· <u>·</u>		·		
Cc: Myles, Renate (NIH)	/OD) [E] <u>k</u>	Meltzer	, Abbey (FNIH	) [T] <b>b6</b>	; Who	lley, David
(FNIH) [T] <b>b6</b>			,			
Bcc: Stoffels, Paul 🔙		b6 NIH/NHLBI) [E] inet (FDA/CDER)	Fau	ci, Anthony (NIH	I/NIAID) [E]	
<b>b6</b>	Gibbons, Gary (	NIH/NHLBI) [E]	b6	; Pao, Wi	illiam	
DO	; Woodcock, Ja	net (FDA/CDER)	b6	; A	<u>nnunziato, Pa</u>	<u>ula</u>
b6	Arvin,	Ann h6	; Buc	hbinder, Susan		
b6	; Corey, L	arry DO	; Dav	is, Mark	b6	Emini,
Emilio	b6	; Hanon, Emmanı	ıel	b6	; Haynes,	Barton
b6	Hotez, Peter	b6	Jansen, Kathr	in [	b6	
Lanzavecchia, Antonio	b6	Lowy, Doug	glas (NIH/NCI)	[E] <b>b</b>	6 N	Narks, Peter
(FDA/CBER) {	b6	Mascola, John	b6	; Messor	nnier, Nancy	
(CDC/DDID/NCIRD/OD)	< b6	Offit, Paul	b6	; Parker, Ash	ley (NIH/OD) [	E]
b6	⟩; Santos, Michae	el (FNIH) [T]	b6 ;	Santos, Nancy	b6	
b6 b6 Emilio   b6 Lanzavecchia, Antonio   (FDA/CBER) { (CDC/DDID/NCIRD/OD) b6 Schuitemaker, Hanneke  >btolman@deloitte.cor Michael, Nelson,	b6	; Tartaglia, Jir	n [	b6	; Tolman, Bre	tt
 btolman@deloitte.cor	n>; Zaks, Tal {	b6	Qashu, Fe	licia (NIH/OD) [E	] k	6
Michael, Nelson,	b6	; Adam, Sta	acey (FNIH) [T	b6	; Bascles,	Lionel
Desrosiers , Betsy Doroshow, James (NIH)	Cohen, M	yron	b6	Corey, Larry	/ <b>b</b>	6 ;
Desrosiers , Betsy	b6	Dicke	ns, Jim (NIH/N	CATS) [C]	b6	þ;
Doroshow, James (NIH/	NCI) [E]	<b>b6</b> Go	ff, David (NIH,	/NHLBI) [E]	b6	; Heaton,
renny: <b>bb</b>	i	irilia. iviike i	b6 ! N:	avak. Seema uui	H/NIAID) IEI	
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b6	; Stein,	(NIH/OD) [E] { aura { b Peter (FDA/CDER) [ b6	b6	our	ntas, Karen (FN	VIH) [T]
b6	/incent, Mike	b6	; Wach	tel, Jonathan <jv< td=""><td>wachtel@delo</td><td>itte.com&gt;;</td></jv<>	wachtel@delo	itte.com>;
Woodcock, Janet (FDA/	CDER	b6		į.	Sizemore, Ch	ristine
(NIH/FIC) [E] {	b6	; Victoria Davey	b6	; Qash	u, Felicia (NIH	/OD) [E]
b6	_; Weinmann,	b6	>; Mens	ah, {	b6	
Adam, Stacey (FNIH) [T]	b6	;; Bozzette, Sam (N	IH/NCATS) [E]	b6	; Bu	chman, Tim
(OS/ASPR/BARDA) (CTR	) < <b>b6</b>	Buttertor	n, Joan	b6	; Curr	ier, Judy
D6	; De Claro, F	R. Angelo (FDA/CDEF	R)	b6	; Draghia-A	kli, Ruxandra
b6	; Eisner, Mark	b6	⟩; Garner,			
Carlos b6	Gotte	sdiener, Keith	b6	j; H	lughes, Eric	
b6	; Kim, Elizab	eth <elkim@deloitte< td=""><td>com&gt;; LaVan</td><td>ge, Lisa</td><td>b6</td><td>Levy, Elliot</td></elkim@deloitte<>	com>; LaVan	ge, Lisa	b6	Levy, Elliot
b6 ;	Mellors, John					
Ashley (NIH/OD) [E]	<b>b6</b> Poole	; Patel, Naimish	L	b6	; Peppercorn,	Amanda
b6 '	Poole	, Mike {	b6	; Prosc	han, Michael	
b6	; Read, Sarah			ichael (FNIH) [T]		}Shen,
Yuan Li (FDA/CDER) {	b6	;; Stein, Peter	r (FDA/CDER)			ggs, Elizabeth
b6	]; Koroshetz, Walte	er <b>b6</b>		arley, John	b6	
	b6	Qashu Reineck, Lora	ı, Felicia	b6	; Burgess,	
Timothy <b>t</b>	) <b>6</b> ; F	lainaak Lara!	L.C	i. Agganwal N	أبانه	<b>b6</b>

Subject: ACTION: Making your ACTIV Participation Public

Dear Colleagues:

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer and David Wholley by 3:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed as part of the ACTIV membership.

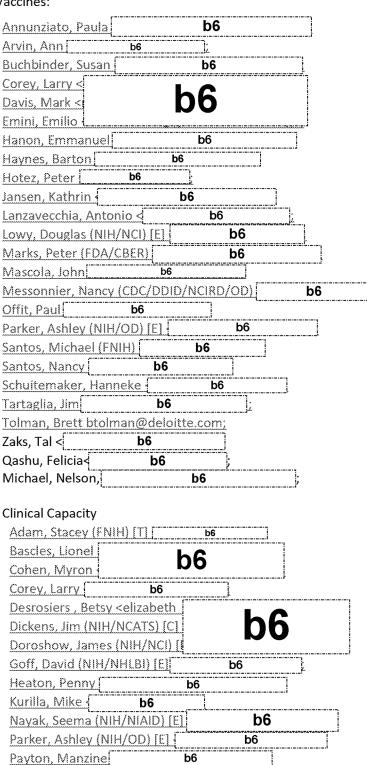
Thanks, Francis

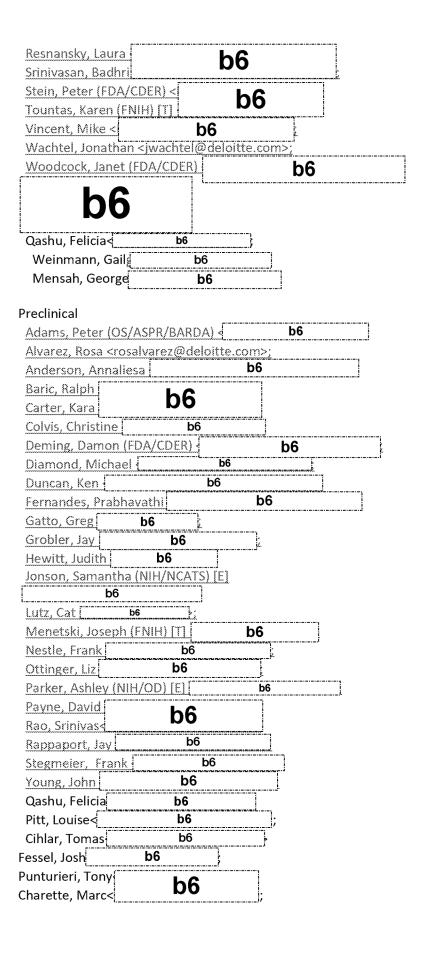
Francis Collins, MD, PhD NIH Director From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS] Sent: 5/14/2020 2:05:10 PM To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc] RE: JAMA Viewpoint on ACTIV: please review Subject: That's fine - thanks! I am packaging the email to make it easy for Francis to send. Ashley From: Wholley, David (FNIH) [T] Sent: Thursday, May 14, 2020 9:32 AM **b6** Melencio, Cheryl (FNIH) [T] To: Parker, Ashley (NIH/OD) [E] b6 Subject: RE: JAMA Viewpoint on ACTIV: please review I think I just forwarded Cheryl's email to you on to Francis. Is that what you wanted? From: Parker, Ashley (NIH/OD) [E] Sent: Thursday, May 14, 2020 9:14 AM To: Melencio, Cheryl (FNIH) [T] Cc: Wholley, David (FNIH) [T] Subject: Re: JAMA Viewpoint on ACTIV: please review Hi Cheryl, I'm on a ICD call with Francis, can you please send him the list of emails? Thanks! Ashley On May 14, 2020, at 9:10 AM, Melencio, Cheryl (FNIH) [T] wrote: Hi Ashley I have added those who have been added to the working groups since Tuesday. Cheryl Chervl Melencio Administrative Manager, Research Partnerships Foundation for the National Institutes of Health b6 fnih.org 11400 Rockville Pike Suite 600 North Bethesda, MD 20852 Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic <image002.png>

From: Parker, Ashley (NIH/OD) [E]	b6						
<b>Sent:</b> Wednesday, May 13, 2020 10	):10 PM						
<b>To:</b> Wholley, David (FNIH) [T]	b6	]; Melenc	io, Cheryl (FN	liΗ) [T]	b	6	}
Subject: DE: IANAA Viewneint on AA	TIV: place rovi	0147		\			

Here is what Cheryl provided as of Friday – she may have additional updates.

#### Vaccines:





Adam, Stacey (FNIH) [T] <b>b6</b>	
Bozzette, Sam (NIH/NCATS) [E] [	<b>b6</b>
Buchman, Tim (OS/ASPR/BARDA) (CTR	
Butterton, Joan <b>b6</b>	
Currier, Judy b6	
De Claro, R. Angelo (FDA/CDER)	b6
Draghia-Akli, Ruxandra <b>b6</b>	
Eisner, Mark <b>b6</b>	
Garner, Carlos <b>b6</b>	
Gottesdiener, Keith <b>b6</b>	
Hughes, Eric < <b>b6</b>	
Kim, Elizabeth <elkim@deloitte.com>;</elkim@deloitte.com>	
LaVange, Lisa <b>b6</b>	
Levy, Elliot <b>b6</b> ;	
Mellors, John <b>b6</b>	
Menon, Sandeep <b>b6</b>	
Parker, Ashley (NIH/OD) [E]	b6
Patel, Naimish b6	
Peppercorn, Amanda k	b6
Poole, Mike <b>b6</b>	
Proschan, Michael b6	
Read, Sarah <b>b6</b>	
Santos, Michael (FNIH) [T]	<b>b6</b>
Shen, Yuan Li (FDA/CDER)	
Stein, Peter (FDA/CDER) <b>b</b> 0	6
Higgs, Elizabeth <b>b6</b>	
Koroshetz, Walter <b>b6</b>	
Farley, John <b>b6</b>	
<b>b6</b>	
<u>                                     </u>	·
Qashu, Felicia b6	<u></u>
Burgess, Timothy b6	
Reineck, Lora<	
Aggarwal, Neil	
From: Wholley, David (FNIH) [T]	b6
Sent: Wednesday, May 13, 2020 10:04 F	PM:
Fo: Melencio, Cheryl (FNIH) [T]	<b>b6</b>
Cc: Parker, Ashley (NIH/OD) [E] Subject: FW: JAMA Viewpoint on ACTIV:	· nlesse review
oubject. Fvv. JAIVIA VIEWPOINT ON ACTIV	. picase review
Please help, tx	
. Ioude Help, or	
From: Collins, Francis (NIH/OD) [E]	b6
From: Collins, Francis (NIH/OD) [E] { Sent: Wednesday, May 13, 2020 6:37 PN	··
Fo: Myles, Renate (NIH/OD) [E]	<b>b6</b> Parker, Ashley (NIH/OD) [E]
	ecca (NIH/OD) [E] <b>b6</b>
i, noiseig, nest	, 00/[[-]]

Cc: Burklow, John (NIH/OD) [E] b6 Tabak, Lawrence (NIH/OD) [E]
b6; Wholley, David (FNIH) [T]b6Melencio, Cheryl (FNIH) [T]b6; Parker, Ashley (NIH/OD) [E]b6
b6 ; Parker, Ashley (NIH/OD) [E] b6
Subject: RE: JAMA Viewpoint on ACTIV: please review
I'm glad to send the query if someone will draft the message and someone else (Cheryl?) will
send me the list of e-mails for all of the WG members.
From: Myles, Renate (NIH/OD) [E] <b>b6</b>
<b>Sent:</b> Wednesday, May 13, 2020 6:12 PM
To: Collins, Francis (NIH/OD) [E] b6 ; Parker, Ashley (NIH/OD) [E]
; Kolberg, Rebecca (NIH/OD) [E] { b6
To: Collins, Francis (NIH/OD) [E] b6 ; Parker, Ashley (NIH/OD) [E] b6 ; Kolberg, Rebecca (NIH/OD) [E] b6 ; Tabak, Lawrence (NIH/OD) [E] b6 ; Wholley, David (FNIH) [T] b6
b6 ;; Wholley, David (FNIH) [T] b6
Subject: RE: JAMA Viewpoint on ACTIV: please review
No surprise there. We need to get permission from the EC/WG members quickly. What's the best way to
do this?
Renate Myles, MBA
Deputy Director for Public Affairs Office of Communications and Public Liaison
National Institutes of Health
Tel: b6
From: Collins, Francis (NIH/OD) [E] <b>b6</b>
<b>Sent:</b> Wednesday, May 13, 2020 5:48 PM
Sent: Wednesday, May 13, 2020 5:48 PM  To: Parker, Ashley (NIH/OD) [E] b6   ; Kolberg, Rebecca (NIH/OD) [E]
i he
Cc: Myles, Renate (NIH/OD) [E] b6 Burklow, John (NIH/OD) [E] b6; Tabak, Lawrence (NIH/OD) [E] b6; Wholley, David
b6 ; Tabak, Lawrence (NIH/OD) [E] b6 ; Wholley, David
(FNIH) [T]
Subject: FW: JAMA Viewpoint on ACTIV: please review
Subject: W. Shirit Viewpoint on North. please review
Hey Ashley and Rebecca,
They Ashley and Nebecca,
Can you give these galley proofs a very close read, and let me know if you find anything amiss?
Renate, note that they are asking for the ACTIV website URL. Very timely, I'd say!
Francis
From: Stacy Christiansen <b>b6</b>
Sent: Wednesday, May 13, 2020 5:22 PM
Sent: Wednesday, May 13, 2020 5:22 PM  To: Collins, Francis (NIH/OD) [E] b6
Sent: Wednesday, May 13, 2020 5:22 PM  To: Collins, Francis (NIH/OD) [E] b6  Cc: Howard Bauchner b6 ; Karen Bucher
Sent: Wednesday, May 13, 2020 5:22 PM  To: Collins, Francis (NIH/OD) [E] b6  Cc: Howard Bauchner
Sent: Wednesday, May 13, 2020 5:22 PM  To: Collins, Francis (NIH/OD) [E] b6  Cc: Howard Bauchner b6 ; Karen Bucher

Dear Dr Collins,

Attached please find a proof of your Viewpoint for JAMA on the ACTIV initiative. We have typeset your figure herein, and I am cc'ing the illustrator, Karen Bucher, so we can handle any text or graphics changes simultaneously.

The only query to you is the completion of reference 5, the ACTIV portal URL.

I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly.

Thank you so much!
Best, Stacy
Stacy L. Christiansen, MA
Managing Editor, JAMA
Chair, AMA Manual of Style

<image001.jpg>

**Sent**: 5/14/2020 2:10:12 PM

CC:

To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: RE: JAMA Viewpoint on ACTIV: please review

Thanks, David. Francis – I am connecting with Renate to get an updated time on the request to have the responses back from the ACTIV EC and WG members. I will package the draft message along with the emails to make it easy for you to send.

From: Wholley, David (FNIH) [T]	b6	
<b>Sent:</b> Thursday, May 14, 2020 9:29 AM		
To: Collins, Francis (NIH/OD) [E]	h6	
Cc: Parker, Ashley (NIH/OD) [E] <	b6	; Melencio, Cheryl (FNIH) [T] <b>b6</b>
Subject: FW: JAMA Viewpoint on ACTI\	/: please review	ti

As requested by Ashley

From: Melencio, Cheryl (FNIH) [T]	b6	
Sent: Thursday, May 14, 2020 9:10	) AM	_
To: Parker, Ashley (NIH/OD) [E]	b6	]
Cc: Wholley, David (FNIH) [T]	b6	
Subject: RF: IAMA Viewpoint on A	CTIV: please review	

I have added those who have been added to the working groups since Tuesday.

Cheryl

Hi Ashley

Cheryl Melencio

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

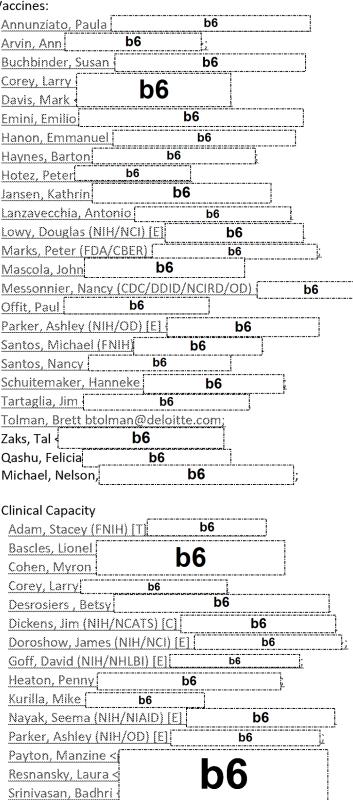
Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

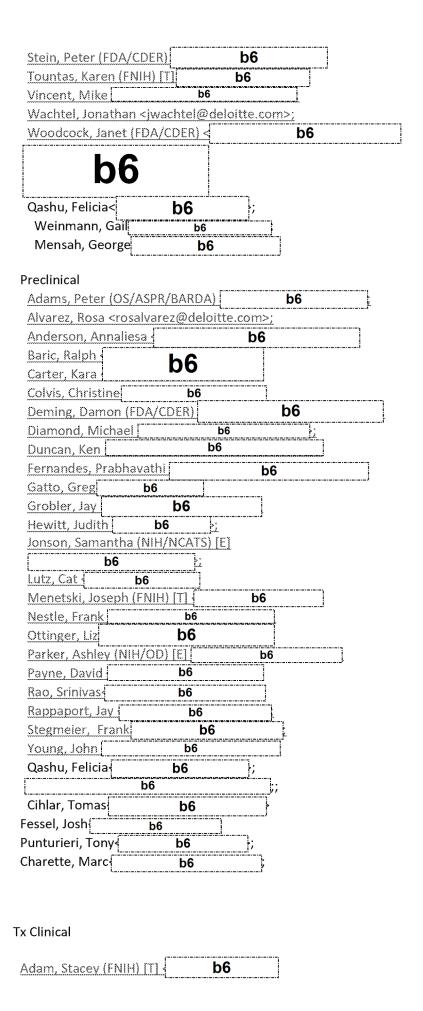


From: Parker, Ashley (NIH/OD) [E]	b6			
<b>Sent:</b> Wednesday, May 13, 2020 10:10 PM				
To: Wholley, David (FNIH) [T] b6		; Melencio, Cheryl (FNIH) [T]	b6	
Subject: RE: IAMA Viewpoint on ACTIV: place	ca ravi	(		

Here is what Cheryl provided as of Friday – she may have additional updates.

# Vaccines:





Bozzette, Sam (NIH/NO	CATS) [E] {	b6			
Buchman, Tim (OS/ASI	PR/BARDA) (CTR)	<u>.</u>	06		
Butterton, Joan	b6				
Currier, Judy	b6				
De Claro, R. Angelo (FL	DA/CDER)	b6			
Draghia-Akli, Ruxandra		**************************************	r		
Eisner, Mark	b6				
Garner, Carlos	b6				
Gottesdiener, Keith	b6		₁		
Hughes, Eric <d< td=""><td>b6</td><td></td><td>J</td><td></td><td></td></d<>	b6		J		
Kim, Elizabeth <elkim@< td=""><td></td><td><u>i</u></td><td></td><td></td><td></td></elkim@<>		<u>i</u>			
LaVange, Lisa {	b6				
L	06 <u></u>				
	b6 <u> </u>	·····			
Menon, Sandeep		b6			
Parker, Ashley (NIH/OI			سا		
Patel, Naimish L	b6				
Peppercorn, Amanda	b	6	. <u></u> j		
Poole, Mike	b6	<u></u>			
<u>Proschan, Michael [</u>	b6	<u></u> j			
Read, Sarah	b6 ;				
Santos, Michael (FNIH)		<u> </u>	<del></del> j		
Shen, Yuan Li (FDA/CD		b6			
Stein, Peter (FDA/CDE	<u>₹}</u> b6				
Higgs, Elizabeth 🚛	b6	<u>;</u>			
Koroshetz, Walter	b6				
Farley, John ₹	b6	]			
b6					
Qashu, Felicia	b6				
Burgess, Timothy	b6	}			
	b6				
Reineck, Lora	b6	- <u>1</u>			
Aggarwal, Neil	DO	!			
<b>'om:</b> Wholley, David (F	NIH) [T]	b6			
ent: Wednesday, May		M			
<b>o:</b> Melencio, Cheryl (Fl		b6			
c: Parker, Ashley (NIH/					
ubject: FW: JAMA Viev	vpoint on ACTIV:	please review	•		
laasa hala 🐯					
lease help, tx					
rom: Collins, Francis (N	IIH/OD) [E]	b6			
ent: Wednesday, May			i		
o: Myles, Renate (NIH)		b6	; Parker, Ashley (NIH/OD) [E]	b6	; Kol
				~~	: , 1.01
	b6				J
ebecca (NIH/OD) [E] ( c: Burklow, John (NIH/	b6	b6	Tabak, Lawrence (NIH/OD) [E]	b6	

m glad to send the query if some	ne will draft	the message and someone else (Che	rvl?) will sen	d me the lis
f e-mails for all of the WG membe		the message and someone else (ene	i yi: j wiii scii	a me me m
e mans for an or the wo membe	.13.			
om: Myles, Renate (NIH/OD) [E]	b6			
ent: Wednesday, May 13, 2020 6:12	PM			
o: Collins, Francis (NIH/OD) [E]	b6	Parker, Ashley (NIH/OD) [E]	b6	Kolberg
ebecca (NIH/OD) [E] 🔙 🔻 <b>b6</b>		<u>-</u>		
: Burklow, John (NIH/O <u>D) [E]</u>		; Tabak, Lawrence (NIH/OD) [E]	b6	j;
holley, David (FNIH) [T] <b>b6</b>	i			
<b>bject:</b> RE: JAMA Viewpoint on ACTIV	/: please revie	eW		
surprise there. We need to get per	mission from	the EC/WG members quickly. What's the	e best way to	do this?
nale Myles, MBA				
epuly Director for Public Affairs				
tice of Communications and Public L	iaison			
d <u>ional Institutes</u> of Health				
† <b>b6</b> j				
om: Collins, Francis (NIH/OD) [E]				
ent: Wednesday, May 13, 2020 5:48		r		
: Parker, Ashley (NIH/OD) [E]		>; Kolberg, Rebecca (NIH/OD) [E] Burklow, John (NIH/OD) [E]	b6	<u>.</u>
: Myles, Renate (NIH/OD) [E]	NO.	Burklow, John (NIH/OD) [E]	b6	Tabak,
	;	Wholley, David (FNIH) [T] <b>b6</b>		
wrence (NIH/OD) [E] b6				
wrence (NIH/OD) [E] b6  Ibject: FW: JAMA Viewpoint on ACTI	V: please revi	ew		
wrence (NIH/OD) [E] b6 white the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of the base of t	V: please revi	iew		
ubject: FW: JAMA Viewpoint on ACTI ey Ashley and Rebecca,	V: please revi	ad, and let me know if you find anyth	ning amiss?	
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ey Ashley and Rebecca, an you give these galley proofs a venate, note that they are asking for ancis  om: Stacy Christiansen	V: please revi very close re or the ACTIV	ad, and let me know if you find anyth	ing amiss?	
ey Ashley and Rebecca,  an you give these galley proofs a venate, note that they are asking for ancis  om: Stacy Christiansen {  int: Wednesday, May 13, 2020 5:22	V: please revi very close re or the ACTIV	ad, and let me know if you find anyth	ning amiss?	
ey Ashley and Rebecca,  an you give these galley proofs a venate, note that they are asking for	V: please revi very close re or the ACTIV	ad, and let me know if you find anyth	iing amiss?	

Dear Dr Collins,

Attached please find a proof of your Viewpoint for JAMA on the ACTIV initiative. We have typeset your figure herein, and I am cc'ing the illustrator, Karen Bucher, so we can handle any text or graphics changes simultaneously.

The only query to you is the completion of reference 5, the ACTIV portal URL.

I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly.
Thank you so much!
Best, Stacy
Stacy L. Christiansen, MA
Managing Editor, JAMA
Chair, AMA Manual of Style



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]

**Sent**: 5/14/2020 2:32:15 PM

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: RE: JAMA Viewpoint on ACTIV: please review

Thanks. I am looping in Abbey so that she will be aware the an email will go out with her name on the cc line. That was my purpose for cc'ing Abbey.

From: Melencio, Cheryl (FNIH) [T] b6

Sent: Thursday, May 14, 2020 10:29 AM

To: Parker, Ashley (NIH/OD) [E] b6

Subject: RE: JAMA Viewpoint on ACTIV: please review

Ashley

I sent the updated working group member list to Abbey Meltzer a little while ago.

#### Cheryl Melencio

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E]	b6	<b></b>		
<b>Sent:</b> Thursday, May 14, 2020 10:20 AM				
To: Collins, Francis (NIH/OD) [E]	b6	Myles, Renate (NIH/OD) [E]	b6	; Kolberg,
Rebecca (NIH/OD) [E] b6		·		
Cc: Burklow, John (NIH/OD) [E]	b6	Tabak, Lawrence (NIH/OD) [E]	] [	b6
Wholley, David (FNIH) [T] b6	}; N	1elencio, Cheryl (FNIH) [T]	b6	; Meltzer, Abbey
(FNIH) [T] [		<u> </u>		≟

Subject: RE: JAMA Viewpoint on ACTIV: please review

To be clear the new WG members are on this email thread below but we will need to add them to draft webpage once we have permission to list their names.

+ Abbey.

Thanks,

Ashley

From: Parker, Ashley (NIH/OD) [E]				
<b>Sent:</b> Thursday, May 14, 2020 10:16 AM				
To: Collins, Francis (NIH/OD) [E]	b6	; Myles, Renate (NIH/OD) [E]	b6	; Kolberg,
Rebecca (NIH/OD) [E] <b>b6</b>				·
Cc: Burklow, John (NIH/OD) [E] {	b6	Tabak, Lawrence (NIH/OD) [E]		b6
Wholley, David (FNIH) [T] b6		; Melencio, Cheryl (FNIH) [T] b6	Þ	i
Subject: RE: JAMA Viewpoint on ACTIV: p	olease	review		

Hi Francis,

David forwarded the emails this morning. Please see below to make it easy to send.

I've pasted a slightly revised draft email OCPL provided (to also cc Renate, Abbey and David?). Renate – there are a few new members working group members, we can work together to update the list.

То:					
Cc: Myles, Renate (NIH/	/OD) [E] <b>b6</b>	: Meltzer.	Abbev (FNIH) [T]	b6 W	/hollev. David
	/	p/p/			,,
Bcc: Stoffels, Paul ₹	b	6	Fauci, Antho	ony (NIH/NIAID) [E]	1
[	Sibbons, Gary (NII	1/NHLBI) [E] ﴿	b6 };	Pao, William	•
<b>b</b> 6	; Woodcock, Jane	(FDA/CDER)	b6	Annunziato,	Paula
b6	Arvin, An	n be	; Buchbinder,	Susan	
b6	Arvin, An Corey, Larry	,, <b>b6</b>	; Davis, Mark	b6	>; Emini,
Emilio   b6  Emilio   b6  Lanzavecchia, Antonio   (FDA/CBER)   (CDC/DDID/NCIRD/OD)   b6	<b>b6</b>	Hanon, Emmanue	l b6	>; Hayne	es, Barton
b6	; Hotez, Peter	b6 Ja	ansen, Kathrin 🖣	b6	};
Lanzavecchia, Antonio [	b6	; Lowy, Dougla	as (NIH/NCI) [E]	b6	; Marks, Peter
(FDA/CBER)	<b>b6</b> ; Ma	scola, John {	b6 ;	Messonnier, Nand	 Sy
(CDC/DDID/NCIRD/OD)	<b>d b6</b> C	Offit, Paul	ь6 ; Park	er, Ashley (NIH/O	D) [E]
ь6 Schuitemaker, Hanneke	;; Santos, Michael (F	NIH) [T] k	; Santos, I	VancyI	b6
Schuitemaker, Hanneke	b6	; Tartaglia, Jim	< b6	Tolman, I	Brett
<pre><btolman@deloitte.cor< pre=""></btolman@deloitte.cor<></pre>	n>; Zaks, Tal 🖣	b6	Qashu, Felicia (NIH	/OD) [E] [	b6
<a href="mailto:cormonichael">btolman@deloitte.cor</a> Michael, Nelson,	b6	Adam, Stac	ey (FNIH) [T]	b6 ; Bascl	es, Lionel
Desrosiers , Betsy Doroshow, James (NIH/	; Cohen, Myrc	n be	; Core	ey, Larry ﴿	b6
Desrosiers , Betsy	b6	Dickens	, Jim (NIH/NCATS) [C	] {b6	auguauguauguaugu
Doroshow, James (NIH/	'NCI) [E] 🗧k	Goff	, David (NIH/NHLBI) [	E] <b>b6</b>	Heaton,
Penny b6	Kurill	a, Mike <b>b6</b>	; Nayak, See	ema (NIH/NIAID) [I	E]
h6	Parker, Ashley (NII	H/OD) [E] [	<b>b6</b> ; Pay	yton, Manzine	
DO	: Resnansky, Laur	b6	Sriniva	san, Badhri	
b6	Rurill Parker, Ashley (NII Resnansky, Laurill ; Stein, Pe /incent, Mike CDER)	ter (FDA/CDER)	b6	<u>  Karen</u>	<u>(FNIH) [T]</u>
b6 ;; V Woodcock, Janet (FDA/ (NIH/FIC) [E]   b6 Adam, Stacey (FNIH) [T] (OS/ASPR/BARDA) (CTR  b6 b6	/incent, Mike	b6	; Wachtel, Jona	than < <u>iwachtel@d</u>	leloitte.com>;
Woodcock, Janet (FDA/	CDER)	b6		; Sizemore,	Christine
(NIH/FIC) [E] <	b6 ;	Victoria Davey {	b6	]; Qashu, Felicia (N	VIH/OD) [E]
b6	); Weinmann,	b6	; Mensah,	b6	
Adam, Stacey (FNIH) [T]	b6	Bozzette, Sam (NIF	I/NCATS) [E] {	b6	Buchman, Tim
(OS/ASPR/BARDA) (CTR	) <b>b6</b>	Butterton,	Joan J	<b>36</b> C	urrier, Judy
√ b6	; De Claro, R. A	ngelo (FDA/CDER)	b6	; Draghi	ia-Akli, Ruxandra
b6	}; Eisner, Mark	b6	; Garner,		
Caulan h6	! Cattanal:		h.C	Hughes, Eric	<u> </u>
b6	l. Kim Elizahath	-allien adalaitta a	om>; LaVange, Lisa [	b6	Levy, Ellio
Ashley (NIH/OD) [E]	b6 ; Poole, M	}; Patel, Naimish	b6	; Pepperco	rn, Amanda
b6	; Poole, M	ike [	b6	💃 Proschan, Micha	ael
b6	Read, Sarah	b6	; Santos, Michael (Fl	MIH) [T] b	6 Shen,

Yuan Li (FDA/CDER) [	b6	>; Steir	n, Peter (FDA/CDE	R) {	b6	
b6	>; Koroshetz, W	/alter	b6	; Farley, John	b6	};
<u> </u>	b6	,	; Qashu, Felicia	b6	Burgess,	
Timothy	b6	; Reineck, Lora	b6	; Aggarwal, Ne	il<	b6

Subject: ACTION: Making your ACTIV Participation Public

## Dear Colleagues:

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed as part of the ACTIV membership.

Thanks, Francis

Francis Collins, MD, PhD NIH Director From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS] Sent: 5/14/2020 2:35:53 PM To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc] Subject: RE: JAMA Viewpoint on ACTIV: please review Yes, I've added them to my email highlighted below. I got some rest last night and I am on top of it - greatly appreciate it the cross checking! Team work! (3) From: Melencio, Cheryl (FNIH) [T] < Sent: Thursday, May 14, 2020 10:31 AM To: Parker, Ashley (NIH/OD) [E] Subject: RE: JAMA Viewpoint on ACTIV: please review Here are the Executive Committee emails: Collins, Francis (NIH/OD) [E] ; Fauci, Anthony (NIH/NIAID) [E] ; Gibbons, ; Stoffels, Paul Gary (NIH/NHLBI) [E] b6 ; Pao, William **b6** Dolsten, Mikael Cheryl Melencio Administrative Manager, Research Partnerships Foundation for the National Institutes of Health b6 fnih.org 11400 Rockville Pike Suite 600 North Bethesda, MD 20852 Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E]	b	6		
Sent: Thursday, May 14, 2020 10:16 AM				
To: Collins, Francis (NIH/OD) [E]	b6	; Myles, Renate (NIH/OD) [E]	b6	; Kolberg,
Rebecca (NIH/OD) [E b6	þ			
Cc: Burklow, John (NIH/OD) [E]	b6	; Tabak, Lawrence (NIH/OD) [E]	b6	}
Wholley, David (FNIH) [T] <b>b6</b>		, Melencio, Cheryl (FNIH) [T] <b>b6</b>		
Subject: RE: JAMA Viewpoint on ACTIV: p	lease i	review	<del>-</del>	

Hi Francis,

David forwarded the emails this morning. Please see below to make it easy to send.

I've pasted a slightly revised draft email OCPL provided (to also cc Renate, Abbey and David?). Renate – there are a few new members working group members, we can work together to update the list.

То:	(						
Cc: Myles, Renate (NIH/O	D) [E] <b>b</b>	6 M	eltzer, Abbey	/ (FNIH) [T]	b6	ː; Wholle	ey, David
(FNIH) [T] b6  Bcc: Stoffels, Paul							
Bcc: Stoffels, Paul		b6		Fauci, Anth			
b6	Gibbons, Gary (N	NH/NHLBI) [E		b6 }	; Pao, Willia	am	
1	Gibbons, Gary (N ; Woodcock, Jar	net (FDA/CDEI	₹)[	b6	Ann	unziato, Paul	<u>a</u>
b6	Arvin, A	Ann	h6	ື່; Buchbinder	r, Susan		
b6	; Corey, La	rry <	DO	; Davis, Marl	k [	b6	; Emini,
b6 b6 Emilio { b6	6	🏋; Hanon, Em	manuel[	b6		>; Haynes, B	arton
b6	>; Hotez, Peter <	b6	; Jansen	, Kathrin {	b6	Manahamamamamana,	<b>▶</b> ;
Lanzavecchia, Antonio	b6	>; Lowy	, Douglas (NII	H/NCI) [E] 💹	b6	Ma	arks, Peter
(FDA/CBER)	b6	Mascola, John		b6	; Messonni	er, Nancy	
(CDC/DDID/NCIRD/OD) ₹	<b>b6</b>	; Offit, Paul 🗒	b6	>; Par	ker, As <u>hley</u>	(NIH/OD) [E	]
b6 }	; Santos, Michael	<u>(FN</u> IH) [T]	b6	; Santos,	, Nancy [	b6	<u> </u>
Schuitemaker, Hanneke	<b>b6</b>	>; Tartag	lia, Jim 🚰 🚟	b6		olman, Brett	
 btolman@deloitte.com	>; Zaks, Tal र्	b6	; Qas	shu, Felicia (NI	H/OD) [E] <	b(	}
Michael, Nelson,	b6	; Ada	m, Stacey (FN	√IH) [Τ] {	b <b>6</b>	]; Bascles, Li	onel
b6	; Cohen, My	ron ₹	b6	Co	rey, Larry [	b6	}
Desrosiers , Betsy	b6	>;	Dickens, Jim	(NIH/NCATS) [	C] {	b <b>6</b>	;
Doroshow, James (NIH/N	CI) [E]	b6	]; Goff, Davi	d (NIH/NHLBI)	[E] <b>⟨</b>	b6	; Heaton,
Penny <b>b6</b>	; Kur	illa, Mike 🚛	b6	Nayak, Se	eema (NIH/I	NIAID) [E]	
b6 Lanzavecchia, Antonio [ (FDA/CBER) [ (CDC/DDID/NCIRD/OD)   b6 Schuitemaker, Hanneke   <btolman@deloitte.com> Michael, Nelson,   b6 Desrosiers , Betsy   Doroshow, James (NIH/N) Penny   b6  b6 b6 , Vir</btolman@deloitte.com>	Parker, Ashley (1	NIH/OD) [E]	b6	}; Pa	ayton, Man	zine	
Į	្ទ់>; Resnansky, La	ura [	b6	>; Sriniv	asan, Badh	ri	
b6	; Stein,	Peter (FDA/CI	DER) [	b6	/Tounta	<u>s, Karen (FNI</u>	H) [T]
<b>b6</b> ; Vir	ncent, Mike [	b6	> ;	Wachtel, Jon	athan < <u>jwa</u>	chtel@deloit	te.com>;
Woodcock, Janet (FDA/CI	DER) <		b6		; Si	zemore, Chri	stine
(NIH/FIC) [E]	b6	; Victoria Da	vey[	b6	; Qashu, I	Felicia (NIH/0	<u>DD) [E] </u>
b6 ; Vir Woodcock, Janet (FDA/CI (NIH/FIC) [E]   b6  >; Adam, Stacey (FNIH) [T]   (OS/ASPR/BARDA) (CTR)   b6	Weinmann,	b6		Mensah, {		b6	
Adam, Stacey (FNIH) [T]	b6	Bozzette, S	am (NIH/NCA	TS) [E] {	b6	>; Buc	hman, Tim
(OS/ASPR/BARDA) (CTR)	b6	; But	terton, Joan [		b <b>6</b>	; Currie	r, Judy
b6	>; De Claro, R.	Angelo (FDA,	/CDER) {	b6		🛚 Draghia-Ak	li, Ruxandra
(OS/ASPR/BARDA) (CTR)   b6     b6     Carlos	; Eisner, Mark 🛄	b6	} G	arner,			
Carlos <b>b6</b>	>Gottes	diener, Keith		b6	; Hug	hes, Eric	
b6	; Kim, Elizabe	th < <u>elkim@de</u>	eloitte.com>;	LaVange, Lisa		b6	Levy, Elliot
<b>b6</b> }; №	Nellors, John [	b6	Menon, Sar	1deep	b6		Parker,
Ashley (NIH/OD) [E]	b6	; Patel, Na	imish {	b6	; P	eppercorn, A	manda
b6	Poole,	Mike (	b6		; Proscha	n, Michael	
b6	; Read, Sarah	b6	; San	tos, Michael (	FNIH) [T] 🛄	b6	Shen,
Yuan Li (FDA/CDER) <	b6	>; Stein,	Peter (FDA/	CDER) {	b6	Higg	s, Elizabeth
<b>b6</b> →; l	Koroshetz, Walte	r <u>                                      </u>	b6	Farley, J	ohn ∢	b6	}
	b6	](	Qashu, Felicia	a b6	>	; Burgess,	!
Timothy b6	; Re	eineck, Lora√_	b6	Agg	arwal, Neil	b	6

Subject: ACTION: Making your ACTIV Participation Public

# Dear Colleagues:

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please** 

send your responses to me, cc'ing Renate Myles, Abbey Meltzer and David Wholley by 12:00 p.m. ET tomorrow,
Friday, May 15, if you agree to be listed as part of the ACTIV membership.

Thanks, Francis

From:	Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent:	5/14/2020 2:37:48 PM
To:	Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject:	RE: JAMA Viewpoint on ACTIV: please review
Ok Great!	
	ley, David (FNIH) [T] <b>b6</b>
	day, May 14, 2020 10:37 AM
	Ashley (NIH/OD) [E] <b>b6</b> JAMA Viewpoint on ACTIV: please review
yes	
From: Parke	r, Ashley (NIH/OD) [E] <b>b6</b>
	day, May 14, 2020 10:34 AM
To: Wholley	, David (FNIH) [T] <b>b6</b>
Subject: RE:	JAMA Viewpoint on ACTIV: please review
Has not gon	e out yet but I've placed everyone's email in the bcc line except for Renate, Abbey, and you. Figured FNIH
would want	to be looped in to those responses as well?
From: Whol	ley, David (FNIH) [T] <b>b6</b>
	day, May 14, 2020 10:29 AM
	Ashley (NIH/OD) [E] <b>b6</b>
Subject: RE:	JAMA Viewpoint on ACTIV: please review
This was ser	at as a .bcc yes?
From: Parke	r, Ashley (NIH/OD) [E] <b>b6</b>
Sent: Thurso	day, May 14, 2020 10:16 AM
	rancis (NIH/OD) [E] b6; Myles, Renate (NIH/OD) [E] b6; Kolberg,
Rebecca (NI	\(
	JAMA Viewpoint on ACTIV: please review  Jabak, Lawrence (NIH/OD) [E] b6  Jabak, Lawrence (NIH/OD) [E] b6  Jabak, Lawrence (NIH/OD) [E] b6  Jabak Lawrence (NIH/OD) [E] b6  Jabak Lawrence (NIH/OD) [E] b6
	vid (FNIH) [T] b6 ; Melencio, Cheryl (FNIH) [T] b6
Subject: RE:	JAMA Viewpoint on ACTIV: please review
Hi Francis,	
David forwa	rded the emails this morning. Please see below to make it easy to send.
=	a slightly revised draft email OCPL provided (to also cc Renate, Abbey and David?). Renate – there are a few
new membe	ers working group members, we can work together to update the list.
To:	
Cc: Myles, R	enate (NIH/OD) [E] <b>b6</b> Meltzer, Abbey (FNIH) [T] <b>b6</b> Wholley, David
(FNIH) [T]	b6

Bcc: Stoffels, Paul	b6				NIH/NIAID) [E	
√ h6	Gibbons, Gary (NIH/	NHLBI) [E] ﴿	b6	Pao	, William	
<b>b6</b>	Gibbons, Gary (NIH/ >; Woodcock, Janet (	FDA/CDER)	b6	5	Annunziato,	<u>Paula</u>
b6	i Arvin, Ann	h6	>; Bu	chbinder, Sus	an	
b6	; Corey, Larry <	DO	>; Da	vis, Mark ∢	b6	; Emini,
Emilio {	b6 ; F	lanon, Emmanu	el	b6	; Hayne	es, Barton
b6  Emilio {  b6  Lanzavecchia, Antonio	; Hotez, Peter	b6 .	lansen, Kath	rin [	b6	
Lanzavecchia, Antonio	b6	}; Lowy, Doug	las (NIH/NCI	) [E]	b6	; Marks, Peter
(FDA/CBER) (CDC/DDID/NCIRD/OD)	<b>b6</b> ; Mas	cola, John [	b6	}; Me	ssonnier, Nand	cy .
(CDC/DDID/NCIRD/OD)	<b>b6</b> ; Off	it, Paul [	b6	}; Parker, /	Ashley (NIH/O	D) [E]
b6	; Santos, Michael (FN	IH) [T]	b6	; Santos, Nan	cy { <b>!</b>	o6 <u>}</u>
Schuitemaker, Hanneke	b6	; Tartaglia, Jim		b6	; Tolman, I	Brett
 btolman@deloitte.com	>; Zaks, Tal	b6	; Qashu, F	elicia (NIH/OD	) [E]	b6
Michael, Nelson, E	b6	; Adam, Sta	cey (FNIH) [٦	[] <b>d</b> b6	; Bascl	es, Lionel
<b>b6</b>	; Cohen, Myron	į.	6	ːːːːːː}; Corey, L	arry {	b6 ;
Desrosiers , Betsy	b6	; Dicken	s, Jim (NIH/	NCATS) [C] ╡¨	b6	;
Doroshow, James (NIH/N	ICI) [E] { <b>b6</b>	þ; Gof	f, David (NIF	√NHLBI) [E] [	b6	; Heaton,
Penny 66	; Kurilla,	Mike b	6 ; N	Nayak, Seema	(NIH/NIAID) [I	E]
Schuitemaker, Hanneke     Schuitemaker, Hanneke     Schuitemaker, Hanneke     Schuitemaker, Hanneke     Michael, Nelson,     b6   Desrosiers , Betsy     Doroshow, James (NIH/N Penny     b6   b6   b6   b6     Schuitemaker, Hanneke     Schuitemaker	Parker, Ashley (NIH/	OD) [E] {	b6	Payton	, Manzine	
Į DU	🎠; Resnansky, Laura 🛚	<b>d</b> b€	3	; Srinivasan	, Badhri	
b6   Vii   Woodcock, Janet (FDA/C (NIH/FIC) [E]	; Stein, Pete	r (FDA/CDER)	be	5	ountas, Karen	(FNIH) [T]
b6 }; Vi	ncent, Mike	b6	; Wac	htel, Jonathar	ı <jwachtel@d< td=""><td><u>leloitte.com</u>&gt;;</td></jwachtel@d<>	<u>leloitte.com</u> >;
Woodcock, Janet (FDA/C	DER)	b6			; Sizemore,	Christine
(NIH/FIC) [E] ₹	<b>b6</b> ; Vi	ctoria Davey	b6	Q	ashu, Felicia (1	VIH/OD) [E]
b6 }	; Weinmann, 🖥	b6	Men	sah,	b6	;
Adam, Stacey (FNIH) [T]	b6 }; Bo	ozzette, Sam (NI	H/NCATS) [E	]	)6 }	Buchman, Tim
(OS/ASPR/BARDA) (CTR)	b6	Butterton,	Joan 📒	b6	; c	Currier, Judy
• b6	; De Claro, R. Ang	gelo (FDA/CDER)	١ ﴿	b6	>; Draghi	ia-Akli, Ruxandra
b6	; Eisner, Mark {	b6	>; Garner	,		
Carlos b6	→Gottesdien	er, Keith	b6		>; Hughes, Erio	<u>c</u>
b6	; Kim, Elizabeth <	<u>elkim@deloitte.</u>	<u>com</u> >; LaVaı	nge, Lisa	b6	>; Levy, Elliot
b6 ; N	Mellors, John 🛴	b6 ; Men	on, Sandeep	[	b6	>; Parker,
Ashley (NIH/OD) [E]	b6	Patel, Naimish [		b6	Pepperco;	rn, Amanda
b6	>; Poole, Mik	e {	b6	; Pr	oschan, Micha	el
b6	; Read, Sarah	b6	Santos, N	/lichael (FNIH)	[T] {	Shen,
Yuan Li (FDA/CDER)	b6	Stein, Peter	(FDA/CDER)	b	6	Higgs, Elizabeth
Yuan Li (FDA/CDER) b6 ;	Koroshetz, Walter	b6		Farley, John {	b6	3
	b6	Qashu,	Felicia	b6	Burges	ss,
Timothy be	Reine	ck, Lora	b6	; Aggarwa	l, Neil	b6

Subject: ACTION: Making your ACTIV Participation Public

# Dear Colleagues:

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed as part of the ACTIV membership.

Thanks, Francis

From: Sent:	Mark Eisner <b>b6</b> 5/14/2020 3:05:28 PM
То:	Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC:	Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
Subject:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd] Re: Time sensitive: Making your ACTIV Participation Public
Subject.	Te. Time sensitive. Making your Activ Fardelpation Fability
Hi Francis,	
, , , , , , , , , , , , , , , , , , ,	
I agree to m	nake my participation public
Mark	
.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Mark D. Eisne	er, MD, MPH
	President, Product Development Immunology, Infectious Disease, and Ophthalmology
Genentech, <u>l</u> i Telenhone:	nc., a member of the Roche Group  b6   Mobile{
For administr	rative assistance, please contact Mary Biggs at:  b6 telephone: b6
tinan.	DO } telephiones[ DO ]
	<u></u>
On Thu, May	y 14, 2020 at 8:00 AM Collins, Francis (NIH/OD) [E] <b>b6</b> wrote:
Dear ACTI	V Colleagues:
Deal Me 11	V Concagues.
37 41 *	
Yes, this me	essage is for you, though your address was in the bcc line!
	like to launch an ACTIV webpage to provide stakeholders with a central resource for information
	forts, including announcements, scientific papers, and new developments. Currently, the content is blicly available information, but we would like add the ACTIV leadership and working group
	our representation on ACTIV demonstrates the breadth and depth of expertise and experience from
	ommitted to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer,
	Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site
as part of t	he ACTIV team.
Thanks,	
Francis	

Francis S. Collins, MD, PhD

NIH Director

From: Sent: To: CC: Subject:	Tartaglia, Jim /US b6 5/14/2020 3:16:10 PM Collins, Francis (NIH/OD) [E] [/o=Exchange (FYDIBOHF23SPDLT)/cn=Recipients/cn=41 Myles, Renate (NIH/OD) [E] [/o=Exchangel (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d [/o=ExchangeLabs/ou=Exchange Administ (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3 [/o=ExchangeLabs/ou=Exchange Administ (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd RE: Time sensitive: Making your ACTIV Par	0e1ca313f44ced9938e50d2ff0b6c2-cd Labs/ou=Exchange Administrative Gro 317f5626934585b3692a1823c1b522- rative Group 41d86cf7404a78ac8f852e698e5382-n rative Group 9e702fcf28414883d0b6996d677257-v	ollinsf] up mylesr]; Meltze neltzerak]; Who	, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,
Dear Dr. Collin	ns: I agree to be listed on the web site	as part of the ACTIV Team. Best re	gards. Jim	
Sent: Thursda	, Francis (NIH/OD) [E] <b>b6</b> ay, May 14, 2020 11:00 AM	}		
•	nate (NIH/OD) [E] <b>b6</b>	; Meltzer, Abbey (FNIH) [T]	b6	; Wholley, David
(FNIH) [T]	b6	<u> </u>		
Subject: [EXTI	ERNAL] Time sensitive: Making your AC	TIV Participation Public		
EXTERNAL	L: Real sender is <b>b6</b>			

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

From: Draghia Akli, Ruxandra [JRDUS] **b6** 

**Sent**: 5/14/2020 3:26:27 PM

To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf] Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Dear Francis – thank you for reaching out.

Yes, it is a privilege to be able to participate on the ACTIV working group, and my name can be included in the posting on the web.

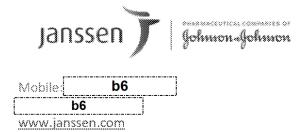
Looking forward to the results, and to delivering solutions to patients. Kind regards, Ruxandra

### Ruxandra Draghia-Akli, MD, PhD

Global Head

CC:

Global Public Health R&D



Confidentiality Notice: This e-mail transmission may contain confidential or legally privileged information that is intended only for the individual or entity named in the e-mail address. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or reliance upon the contents of this e-mail is strictly prohibited. If you have received this e-mail transmission in error, please reply to the sender, so that Johnson & Johnson can arrange for proper delivery, and then please delete the message from your inbox. Thank you.

From: Collins, Francis (NIH/OD) [E]	b6			
<b>Sent:</b> Thursday, May 14, 2020 11:00 AM	_			
To: Collins, Francis (NIH/OD) [E]	<b>56</b>			
Cc: Myles, Renate (NIH/OD) [E]	<b>J</b> O	Meltzer, Abbey (FNIH) [T]	b6	; Wholley, David
(FNIH) [T] <b>b6</b>		t		
Subject: Time sensitive: Making your ACTI	V Participatio	n Public		

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please** 

send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

From:	Amanda Peppercorn <b>b6</b>						
Sent:	5/14/2020 3:59:41 PM						
To:	Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]						
CC:	Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T]						
	[/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T]						
	[/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]						
Subject:	RE: Time sensitive: Making your ACTIV Participation Public						
Yes, you ma	y use my name.						
ъ.							
Best,							
_							
Amanda							
Amanda Pep	ppercorn, M.D.						
GSK Resear	ch & Development						
mobile	<b>b6</b>						
email	DO						
From: Collin	s, Francis (NIH/OD) [E] <b>b6</b>						
	day, May 14, 2020 11:00 AM						
	Tamaia (NIII (OD) [F]						
· ·	enate (NIH/OD) [E]						
	enate (NIH/OD) [E] <b>DO</b> Meltzer, Abbey (FNIH) [T] <b>b6</b> ; Wholley, David						
(FNIH) [T]							
Subject: Tim	ne sensitive: Making your ACTIV Participation Public						

## EXTERNAL

Dear ACTIV Colleagues:

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NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

GSK monitors email communications sent to and from GSK in order to protect GSK, our employees, customers, suppliers and business partners, from cyber threats and loss of GSK Information. GSK monitoring is conducted with appropriate confidentiality controls and in accordance with local laws and after appropriate consultation.

From:	Laura Resnansky	<b>b6</b>			
Sent:	5/14/2020 4:07:32	PM	.4		
То:	Collins, Francis (NI	H/OD) [E] [/o=ExchangeLab	s/ou=Exchange Adr	ministrative Group	
	•	T)/cn=Recipients/cn=410e1		-	
CC:		I/OD) [E] [/o=ExchangeLabs			
	•	T)/cn=Recipients/cn=7d317		2a1823c1b522-mylesr];	Meltzer, Abbey (FNIH) [T]
		ou=Exchange Administrativ		57060805387-maltzara	k]; Wholley, David (FNIH) [T]
	•	ou=Exchange Administrativ		JZEOJOEJSOZ-MERZERA	k], wholey, barid (ritir) [1]
		T)/cn=Recipients/cn=cd9e7	•	6996d677257-wholleyd	<del> </del>
Subject:	•	Making your ACTIV Particip		•	
Hi Francis,					
т 1	1 1 4 1 4	1 4			
I am nappy to	o be listed on the	e web site.			
Post					
Best, Laura					
Laura					
Laura Resnansky					
Therapeutic Area G		y y y considerate			
Immuno <u>logy, Infect</u> mobile <b>b6</b>	tous Diseases, Ophthalm	ology and Neuroscience (I2ON)			
t	/				
			i-		<u>-</u>
On Thu, May	y 14, 2020 at 8:0	0 AM Collins, Francis	(NIH/OD) [E] {	b6	wrote:
			<u>-</u> .		··
Dear ACTI	V Colleagues:				
Vas this me	aggaga ig far van	though your addraga y	yog in the bee lin	na!	
res, unis me	essage is for you	, though your address v	vas in the occ in	ie!	
NIH would	like to launch ar	ACTIV webnage to n	ovide stakehold	ers with a central re	esource for information
					Currently, the content is
		information, but we wo			
					tise and experience from
					Myles, Abbey Meltzer,
					e listed on the web site
	he ACTIV team	_	, x 1 1011y , 11111y x	o, ii you agi ee to k	tisted on the web site
F					
Thanks,					
Francis					

Francis S. Collins, MD, PhD

NIH Director

***************************************		100010010000000000000000000000000000000			
From:	Mike Poole	b6	······································		
Sent:	5/14/2020 4:11:07 PM				
To:	Collins, Francis (NIH/OD) [	E] [/o=Exchang	geLabs/ou=Exchange Administrative Gro	oup	
	(FYDIBOHF23SPDLT)/cn=R	ecipients/cn=4	10e1ca313f44ced9938e50d2ff0b6c2-c	ollinsf]	
CC:	Myles, Renate (NIH/OD) [I	[] [/o=Exchang	eLabs/ou=Exchange Administrative Gro	up	
			'd317f5626934585b3692a1823c1b522-	mylesr]; Melt	zer, Abbey (FNIH) [T]
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	-		341d86cf7404a78ac8f852e698e5382-r	neltzerak]; Wh	nolley, David (FNIH) [T
	[/o=ExchangeLabs/ou=Exc	-	•		
	•		d9e702fcf28414883d0b6996d677257-	wholleyd]	
Subject:	Re: Time sensitive: Making	g your ACTIV Pa	articipation Public		
l agree.					
Mike Poo	le, MD FACP				
	Therapeutics Accelerator	-			
	1elinda Gates Foundation				
Din and it	reminda dates i danidation				
From: Coll	ins, Francis (NIH/OD) [E]	b6			
Sent: Thur	sday, May 14, 2020 8:00 AN	1	·		
To: Collins	, Francis (NIH/OD) [E]	h6			
Cc: Myles,	Renate (NIH/OD) [E] <	<b>b6</b>	; Meltzer, Abbey (FNIH) [T]	b6	; Wholley, David

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

Subject: Time sensitive: Making your ACTIV Participation Public

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

; Wholley, David

Thanks, Francis

From:	Srinivasan, Badhri <b>b6</b>
Sent:	5/14/2020 4:44:17 PM
То:	Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC:	Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject:	Re: Time sensitive: Making your ACTIV Participation Public
Dear Fr	ancis,
Thank y	you for the email and for checking with us.
l agree	to be listed on the web site as part of the ACTIV team.
Regard	S,
Badhri	
	On 14 May 2020, at 17:00, Collins, Francis (NIH/OD) [E] <b>b6</b> wrote:
	on 14 May 2020, at 17.00, Comms, Francis (Min/OD) [c]
	Dear ACTIV Colleagues:
	Yes, this message is for you, though your address was in the bcc line!
	res, this message is for you, though your address was in the DCC line:
	NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for
	information about our efforts, including announcements, scientific papers, and new developments.
	Currently, the content is based on publicly available information, but we would like add the ACTIV
	leadership and working group members. Your representation on ACTIV demonstrates the breadth and
	depth of expertise and experience from all sectors committed to this effort. Please send your responses

to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday,

May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

From:	Menon, Sandeep M <b>b6</b>
Sent:	5/14/2020 5:30:09 PM
То:	Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC:	Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject:	Re: [EXTERNAL] Time sensitive: Making your ACTIV Participation Public
Hi Francis	
Thanks for cl	hecking. I am fine to be included.
Sandeep	
	enon, PhD, MPH
Senior Vice F	President and Head of Early Clinical Development, Pfizer Inc
1 Portland S	treet, Cambridge, MA 02139, USA
Cell: <b>b</b>	6
Email:	b6
L	
From: "Collin	ns, Francis (NIH/OD) [E]" b6
Date: Thurso	day, May 14, 2020 at 11:00 AM
To: "Collins,	Francis (NIH/OD) [E]" b6
Cc: "Myles, F	Renate (NIH/OD) [E]' <b>b6</b> , "Meltzer, Abbey (FNIH) [T]" <b>b6</b>
"Wholley, Da	avid (FNIH) [T]" b6
Subject: [EX	TERNAL] Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

From:	·			NGELABS/OU=EXCHA 8DD7CDCD432E986		
Sent:	5/14/2020 6:0		,			,
To:			changeLabs/ou=	Exchange Administr	ative Group	
				f0679648859e1cf10		sj4]; Eric Hughes
	/					nange Administrative Group
	(FYDIBOHF239			,	-	sa]; Ruxandra Draghia-Akli
	b6	; Mell	ors, John W [/o=	ExchangeLabs/ou=Ex	kchange Administ	rative Group
	(FYDIBOHF239	PDLT)/cn=Recip	ients/cn=user25	cb364]; Naimish Pa	tel <b>b</b>	6 } Young, John
	k	6 ;	Stein, Peter (FDA	/CDER) [/o=Exchang	geLabs/ou=Exchar	nge Administrative Group
	(FYDIBOHF23S	PDLT)/cn=Recip	ients/cn=b4a141	18481b4b39ba7e62	a8d6425f79-Pete	r.Stein]; Poole, Mike
		b6	; Buchman,	Tim (OS/ASPR/BARD	DA) (CTR) [/o=Excl	nangeLabs/ou=Exchange
	Administrative	Group (FYDIBO	HF23SPDLT)/cn=	Recipients/cn=00f8a	853d8d740f8a8c	dd55cbf8eb9da-Tim.Buchman];
	Vincent, Mich	ael	b6	; Keith Gottesdiene	r k	; Elliott Levy
	b6	Wung,	Peter /US	b6	Higgs, Elizabeth	(NIH/NIAID) [E]
	[/o=Exchangel	abs/ou=Exchan	ge Administrative	Group	.i	
	(FYDIBOHF239	PDLT)/cn=Recip	ients/cn=0601ca	55a82841aba16353l	b96cff8ca9-ehiggs	5]
CC:	Elizabeth Kim	[elkim@deloitte	.com]; Menetski,	Joseph (FNIH) [T] [/	o=ExchangeLabs/	ou=Exchange Administrative
	Group (FYDIBO	DHF23SPDLT)/cn	=Recipients/cn=5	001af52dc4a427ea	3d34f1e072f8cb7	-menetskijp]; Alvarez, Rosa
	Maria [rosalva	rez@deloitte.co	m]; Salathin, Car	la	b6	
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	(FYDIBOHF23S	SPDLT)/cn=Recip	ients/cn=306b22	44466140faa95aaaa	afe06ebd70-parke	ras]; Wholley, David (FNIH) [T]
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		_	nange Administra			
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Subject:	•		IV Therapeutics-	Clinical Agent Priori	tization Subgroup	Meeting #5-Including New
	Score Sheet (A	gents Added)				
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=		NOW SEE that it	ocinzamas sina	s to both the mem	ibi ane and the s	oldbie ito Necptor. 30 gets a
both modes o	ir signaling.					
walter						
From: Adam,	StaMycey (FN	IH) [T] [	b6			
Sent: Thursda				_		
To: Eric Hughe	es [	b6	····}; Read, Sara	h (NIH/NIAID) [E] 🖣	b6	; Ruxandra Draghia-
Akli	b6	; Mellors, Jo			Patel {	b6 Colvis,
Christine (NIH	I/NCATS) [E]	b6		ing, John	b6	Stein, Peter
(FDA/CDER)	b6		oole, Mike	h6	· 1	Buchman, Tim
(OS/ASPR/BAI		b6	<u> </u>	ent, Michael	b6	; Keith
Gottesdiener	· · · · · · · · · · · · · · · · · · ·		, Elliott Le			Peter /US
		<u>,</u>				
i	·6	•	alter (NIH/NINI	•		; Higgs, Elizabeth
(NIH/NIAID) [I	-t	:	arlos O Garner		j	·
Cc: Elizabeth I			Menetski, Josep	oh (FNIH) [T] j	b6	Alvarez, Rosa Maria
·		; Salathin, Carl			b6	Parker,
Ashley (NIH/C	DD) [E]	b6	Wholley, [	David (FNIH) [T]	b6	Melencio, Cheryl (FNIH)
[T]	b6	Lucas Smalldor	1	b6	Walke	r, Paula (NIH/NINDS) [E]
b6	3 ;	Ward, Jackie (N	NIH/NINDS) [E]	b6		
Subject: RE: F					itization Subgrou	up Meeting #5-Including New
Score Sheet (A	•		-	-	-	

Hi All,	
This is the second email. It has the anticoag information.	
Thanks, Stacey	
Stacey J. Adam, PhD Director, Cancer Research Partnerships Direct: b6 Mobile: b6	
From: Adam, Stacey (FNIH) [T] Sent: Thursday, April 30, 2020 7:05 PM Subject: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup N Score Sheet (Agents Added) Importance: High	Лeeting #5-Including New
Dear TX-Clinical Agent Prioritization Subgroup, I appreciate the candid and productive meeting that we had today. All your feedback our process for the next time.	is very helpful to refine
For all of you working on scoring right now, please find attached a number of pieces helpful. Some if this some of your groups may have received before, however, I wan whole group for transparency and for having all of our reference data in one place. If ind attached is:  1. The summary spreadsheets for the agents in the host targeted category that have to Consortium group + 1 for b4 as it was requested. (one note, the group shared tested in a few other trials, so that may need to be considered)  2. Articles on the evolving thrombosis issue that doctors are trying to deal with on the previously shared with the Symptomatic/Supportive therapy group.  3. An article relevant to immune modulator use in COVID-19.  4. Articles for the Antiviral group on some preclinical testing work.  5. Also for the antiviral group, the TX-Preclinical team also just sent this link with access which should contain all but b4 are part of the ReFramtested in a SARS-CoV-2 Vero-GFP CPE assay and posted at the Rehttps://reframedb.org/assays/A00440. You can create an account for the steed in a sample of the sample of the group of the sample of the group of the sample of the group of the sample of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of the group of th	the information you will been added from the R&D with us b4 is likely be front lines. These were  ss to more screening data, be library and have been Frame database here free and search the data."  ands added for the groups
Action Items	
Information POC	

1	Provide Review Committee members with 5 compounds for review, along with factsheets from the R&D Consortium	Keith Gottesdiener & Elliott Levy / Stacey Adam
2	Send updated score sheets	Stacey Adam
3	Agent Prioritization Review Committee members (immunomodulators) score additional agents that have been added from the R&D Consortium list	AP Sub Group Members
4	<ul> <li>Getting standardized, reliable data on the agents</li> <li>Trans-NIH information, intramural and extramural</li> <li>Mike Poole, Gates Foundation</li> </ul>	Stacey Adam / Ruxandra Draghia-Akli
5	Ask Preclinical Working Group (R&D members) for relevant data on agents if available	Joe Menetski
6	Get data on antivirals from NIAID and NCATS	Sarah Read/Christine Colvis

# **Key Takeaways**

- We are re-evaluating our list for scoring and adding other agents that were inadvertently left out
- We will not go back and re-evaluate the triage list.
- Sub Group Members voicing concern on lack of confidence in agents they've had to score. More research needed on drugs to understand whether these are worth putting into clinical trials. Need for more data.
- Suggested need to understand value of the agents we are evaluating over remdesivir.

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: **b6** Mobile: **b6** 

fnih.org

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Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



Wung, Peter /US b₆ From: 5/14/2020 6:24:49 PM Sent: To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf] CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd] Subject: RE: Time sensitive: Making your ACTIV Participation Public Dear Francis, Thank you for including me in this important endeavor with the NIH. I am comfortable with my name listed on the website. Regards, Peter Peter K. Wung, MD, MHS, FACR AVP, Global OMD Lead I&I Clinical Sciences & Operations | Research & Development 55 CORPORATE DRIVE - BRIDGEWATER - New Jersey 08807 SANOFI

From: Collins, Francis (NIH/OD) [E]	b6			
Sent: Thursday, May 14, 2020 10:00 AM	1			
To: Collins, Francis (NIH/OD) [E]	h6			
Cc: Myles, Renate (NIH/OD) [E] <	DU	Meltzer, Abbey (FNIH) [T]	<b>b6</b>	; Wholley, David
(FNIH) [T] <b>b6</b>		I		<del>-</del>
Subject: [EXTERNAL] Time sensitive: Ma	king your AC	TIV Participation Public		
EXTERNAL: Real sender is	b6			
i		ــــــــــــــــــــــــــــــــــــــ		

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

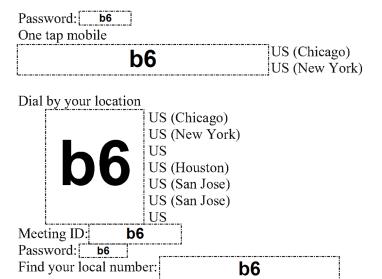
NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on

ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

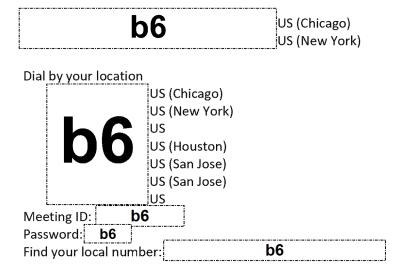
From:			LABS/OU=EXCHANGE ADM 40C04FEF6F1E46F5B75075		
Sent:	5/14/2020 8:36:15 PN	Λ			
To:	Vincent, Mike	b6	; Bascles, Lionel	b6	; Stein, Peter (FDA/CDER)
	[/o=ExchangeLabs/ou	=Exchange Administ	rative Group		<del></del>
	(FYDIBOHF23SPDLT)/	cn=Recipients/cn=b4	la14118481b4b39ba7e62a8	3d6425f79-Pete	r.Stein]; Cohen, Myron
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	(NIH/NCATS) [E] [/o=E	ExchangeLabs/ou=Ex	change Administrative Gro	up	
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	(FYDIBOHF23SPDLT)/	cn=Recipients/cn=51	ld5ee6848004578b5bf9c80	8eca8f6f-nayak	su]; Parker, Ashley (NIH/OD) [E]
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	[b6	; Srinivasan,	d1c1824bfa438a94da8152 Badhri <b>b6</b>	} \	Wachtel, Jonathan
			NIH/OD) [E] [/o=ExchangeL		
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	b6	; Garner, C	arlos <b>b6</b>		, George (NIH/NHLBI) [E]
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	[E] [/o=ExchangeLabs				- , , , , ,
		-	27b160038004a199ae6e0ba	ac2226099-read	sa]; Young, John
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	[marganderson@delc		,		; Melencio, Cheryl (FNIH) [T]
	[/o=ExchangeLabs/ou		1		
				8b628e6f-mele	ncioc]; Collins, Francis (NIH/OD)
	[E] [/o=ExchangeLabs				<b>1</b> , , , ,
		•	.0e1ca313f44ced9938e50d	2ff0b6c2-collins	f]; Gonzalez, Nina
		•	rative Group (FYDIBOHF23:		
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	Hamilton, Nancy b6 ; Minnich, Beth
	[FYDIBOHF23SPDLT]/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Stratton, Benjamin
	[bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Victoria Davey [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da];
	Jintanat Ananworanich b6
Subject:	ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments:	Clinical Trial Capacity Working Group Meeting Agenda_05152020.pdf
Location:	b6
Start:	5/15/2020 1:00:00 PM
End:	5/15/2020 2:00:00 PM
Show Time As:	
Recurrence:	Weekly
Recurrence.	every Tuesday and Friday from 9:00 AM to 10:00 AM
Required	Vincent, Mike; Bascles, Lionel; Stein, Peter (FDA/CDER); Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim
Attendees:	(NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James; Kurilla, Mike; Nayak,
	Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhri; Wachtel,
	Jonathan; Qashu, Felicia
Optional	Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Garner, Carlos; Mensah, George; Weinmann, Gail; Colvis, Christine
Attendees:	(NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] ( b6 ;
	Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos,
	Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth;
	Rebecca (NIH/NCATS) Katz [E] <b>b6</b> Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat
	Ananworanich
Dear Colleagu	ues, Attached is the agenda for this call. Talk with you then. Karen
ACTIV: Acce	elerating COVID-19 Therapeutic Interventions and Vaccines
	8 - 2 - 2 - 2 - 2 - 2 - 2 - 2 - 2 - 2 -
Dear Clinical	Trial Capacity Working Group members,
<b>T</b>	
	n of this working group making rapid progress on identified action items and other activities, the co-chairs
	hat it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify
	and to determine next steps. We ask that you make every effort possible to join each of these meetings, but
	at at times you may have competing priorities. To place a hold on your calendar, please accept this meeting
mvite with a r	response; later you can decline an individual meeting if you have a conflict.
An agenda an	d other meeting materials, as needed, will be distributed prior to each call.
With best rega	ards,
Karen	
Karen H. Tou	ntas, PhD
	gram Manager
	or the National Institutes of Health
T-: 7 M	
Join Zoom M	b6
Meeting ID:	b6



From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP] Sent: 5/14/2020 9:01:45 PM b6 To: USARMY b6 Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Tight of thinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative] Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; b6 Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras); Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm] CC: b6 Rodriguez, Robin D Diamond, Michael Hall, Matthew (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  $(FYDIBOHF23SPDLT)/cn=Recipients/cn=c76a7b2623714aaaa095fda97973f5e6-hallma_b4f6]; Florence, Clint and Comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of the comparison of th$ (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy ; Hughes, Eric **b6** ; Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, ; Rose Li Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes b6 ; Dana Carluccio Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha
	(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
	[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
	Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
	(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Dave Frankowski
	b6 Baric, Toni C b6 Stratton, Benjamin
	[bstratton@DELOITTE.com]
Subject:	RE: ACTIV Preclinical working group (Tuesday meeting)
Attachments:	2020-05-12_Preclinical_WG_Summary_RLA_d3.docx
Dear preclinic	cal working group and invitees,
Please find th	e minutes from our meeting on Tuesday. I apologize for being late (my fault, I am afraid). We look forward
to seeing you	all tomorrow. Please let me know if you have any questions or modifications to these.
Best regards,	
Joe	
_	ppointment
	ski, Joseph (FNIH) [T]
/	y, April 14, 2020 6:43 PM
То:	b6 Tomas Cihlar; b6 USARMY b6
<b>b6</b> (U	SA); Menetski, Joseph (FNIH) [T]; b6
	<b>b6</b>
	b6 Parker, Ashley
	Collins, Francis (NIH/OD) [E]; b6 Adams, Peter (OS/ASPR/BARDA); Rao, nu, Felicia (NIH/OD) [E]
•	Michael; Rodriguez, Robin D; Hall, Matthew (NIH/NCATS) [E]; Florence, Clint (NIH/NIAID) [E]; Lowy,
	/NCI) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T];
	ne (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E];
	s (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey
	nes, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan;
	Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E];
	a; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Dave Frankowski; Baric, Toni C; Stratton,
Benjamin	
Subject: ACTI	V Preclinical working group (Tuesday meeting)
When: Tuesd Where:	ay, May 12, 2020 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada). <b>b6</b>
Holding time	
Joseph Mene	tski is inviting you to a scheduled Zoom meeting.
Join Zoom Me	eeting <b>b6</b>
Meeting ID:	b6
Password:	
One tap mobi	le



From: Penny Heaton Sent: 5/14/2020 10:40:17 PM To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf] CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd] Subject: RE: Time sensitive: Making your ACTIV Participation Public Dear All, Yes – I agree to be listed on the web site as part of the ACTIV team. Best, Penny Penny M. Heaton, MD Chief Executive Officer **Bill & Melinda Gates Medical Research Institute** 245 Main Street, Cambridge, MA 02142 +1 857 301 9404 **b6** Mary Burke Executive Assistant to the CEO **Bill & Melinda Gates Medical Research Institute** 245 Main Street, Cambridge, MA 02142 M E From: Collins, Francis (NIH/OD) [E] b6 **Sent:** Thursday, May 14, 2020 11:00 AM To: Collins, Francis (NIH/OD) [E] **b6** Cc: Myles, Renate (NIH/OD) [E] Meltzer, Abbey (FNIH) [T] **b6** Wholley, David (FNIH) [T] Subject: Time sensitive: Making your ACTIV Participation Public Attention: This message was sent from an external domain. Dear ACTIV Colleagues:

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please** 

Yes, this message is for you, though your address was in the bcc line!

send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

From:	Patel, Naimish /US <b>b6</b>
Sent:	5/15/2020 2:49:06 AM
To:	Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC:	Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject:	Time sensitive: Making your ACTIV Participation Public
Dear Francis	
I would be h	appy to have my name listed on the website.
Best,	
Naimish	
From: "Coll	ins, Francis (NIH/OD) [E]' <b>b6</b>
	sday, May 14, 2020 at 11:03 AM
	, Francis (NIH/OD) [E]" <b>b6</b> "Meltzer Δbbey (FNIH) [T]" <b>b6</b>
Cc: "Myles,	include (Milly Ob) [E] [
"Wholley, [	David (FNIH) [T]" b6
Subject: [EX	KTERNAL] Time sensitive: Making your ACTIV Participation Public
	,
FYTFDNA	L: Real sender is <b>b6</b>
EUA E EUENINA	xa. Real school is UD

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

From:		I/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP I//CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]	
Sent:	5/15/2020 2:50:21	·· · · · · · · · · · · · · · · · · · ·	
To:		/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group	
	(FYDIBOHF23SPDLT	)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Allen-Gifford	d, Patrice
		changeLabs/ou=Exchange Administrative Group	
	•	)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]	
CC:		/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group	<b>~</b> 1
	•	)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wooldridg	e, Shannon
		changeLabs/ou=Exchange Administrative Group )/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]; Pollock, R	achel (NIH/OD)
		bs/ou=Exchange Administrative Group	acrier (WITI) OD)
		)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]; Melencio,	Cheryl (FNIH) [T]
		ou=Exchange Administrative Group	, , , , , , ,
	(FYDIBOHF23SPDLT	)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]	
Subject:	RE: Time sensitive:	Making your ACTIV Participation Public	
I'm agreeing	g with that.		
From: Myles,	Renate (NIH/OD) [	E) <b>b6</b>	
Sent: Thursda	ay, May 14, 2020 1	D:50 PM	
To: Collins, Fr	rancis (NIH/OD) [E]	b6; Allen-Gifford, Patrice (NIH/OD) [E] <patrice.allen-< td=""><td></td></patrice.allen-<>	
b6			
Cc: Parker, As	shley (NIH/OD) [E]	<b>b6</b> ; Wooldridge, Shannon (NIH/OD) [E]	
	b6	b6 ; Wooldridge, Shannon (NIH/OD) [E] ; Pollock, Rachel (NIH/OD) [E] b6 ; Melencio, Chery	ıl (FNIH) [T]
i	UU		
į			
		ring your ACTIV Participation Public	
Subject: RE: 7	Гіте sensitive: Mak		
Subject: RE: 7	Гіте sensitive: Mak	ring your ACTIV Participation Public	
Subject: RE: 1 Can we remo From: Collins	Francis (NIH/OD)	ring your ACTIV Participation Public on't think we need their permissions, right?	
Subject: RE: 1 Can we remo From: Collins	Francis (NIH/OD)	ring your ACTIV Participation Public on't think we need their permissions, right?	
Subject: RE: 1 Can we remo From: Collins	Francis (NIH/OD)	ring your ACTIV Participation Public on't think we need their permissions, right?	
Subject: RE: 1 Can we remo From: Collins	Francis (NIH/OD)	ring your ACTIV Participation Public on't think we need their permissions, right?	
Subject: RE: 1 Can we remo From: Collins Sent: Thursda To: Myles, Re b6	Francis (NIH/OD)	ing your ACTIV Participation Public  n't think we need their permissions, right?  [E] b6  D:49 PM  b6 Allen-Gifford, Patrice (NIH/OD) [E] b6	
Subject: RE: To Can we remo  From: Collins Sent: Thursdator: Myles, Re b6  Cc: Parker, As	Francis (NIH/OD)  ay, May 14, 2020 10  enate (NIH/OD) [E]	ting your ACTIV Participation Public  n't think we need their permissions, right?  [E] b6  D:49 PM  b6 Allen-Gifford, Patrice (NIH/OD) [E] b6	] /l (FNIH) [T]
Subject: RE: To Can we remo  From: Collins Sent: Thursdator: Myles, Re b6  Cc: Parker, As	Fime sensitive: Make we the NIHers? I do , Francis (NIH/OD) ay, May 14, 2020 10 enate (NIH/OD) [E]	ing your ACTIV Participation Public  n't think we need their permissions, right?  [E] b6  D:49 PM  b6 Allen-Gifford, Patrice (NIH/OD) [E] b6  Wooldridge, Shannon (NIH/OD) [E]	d (FNIH) [T]
Subject: RE: To Can we remo  From: Collins Sent: Thursdator To: Myles, Re b6  Cc: Parker, As	Francis (NIH/OD) ay, May 14, 2020 10 anate (NIH/OD) [E] shley (NIH/OD) [E]	ing your ACTIV Participation Public  n't think we need their permissions, right?  [E] b6  D:49 PM  b6 Allen-Gifford, Patrice (NIH/OD) [E] b6  Wooldridge, Shannon (NIH/OD) [E]	] /I (FNIH) [T]
Subject: RE: To Can we remo  From: Collins Sent: Thursdator To: Myles, Re b6  Cc: Parker, As	Francis (NIH/OD) ay, May 14, 2020 10 anate (NIH/OD) [E] shley (NIH/OD) [E]	ting your ACTIV Participation Public  n't think we need their permissions, right?  [E] b6  D:49 PM  b6 Allen-Gifford, Patrice (NIH/OD) [E] b6  Wooldridge, Shannon (NIH/OD) [E]  ; Pollock, Rachel (NIH/OD) [E] b6  ; Melencio, Chery	l d (FNIH) [T]
Subject: RE: To Can we remo  From: Collins Sent: Thursdato: Myles, Re  b6 Cc: Parker, As  Subject: RE: To	Francis (NIH/OD) ay, May 14, 2020 10 enate (NIH/OD) [E] shley (NIH/OD) [E] Time sensitive: Mak	ting your ACTIV Participation Public  n't think we need their permissions, right?  [E] b6  D:49 PM  b6 Allen-Gifford, Patrice (NIH/OD) [E] b6  Wooldridge, Shannon (NIH/OD) [E]  ; Pollock, Rachel (NIH/OD) [E] b6  ; Melencio, Chery	
Subject: RE: To Can we remo  From: Collins Sent: Thursdator To: Myles, Re b6  Cc: Parker, As Subject: RE: To Yes, please series	Francis (NIH/OD) ay, May 14, 2020 10 anate (NIH/OD) [E] shley (NIH/OD) [E] fime sensitive: Makesend an update in	ing your ACTIV Participation Public  n't think we need their permissions, right?  [E] b6  D:49 PM  b6 Allen-Gifford, Patrice (NIH/OD) [E] b6    Wooldridge, Shannon (NIH/OD) [E]  ; Pollock, Rachel (NIH/OD) [E] b6  ; Melencio, Chery  ing your ACTIV Participation Public	
Subject: RE: To Can we remo  From: Collins Sent: Thursda To: Myles, Re	Francis (NIH/OD) ay, May 14, 2020 10 anate (NIH/OD) [E] shley (NIH/OD) [E] fime sensitive: Makesend an update in	ing your ACTIV Participation Public  n't think we need their permissions, right?  [E] b6  D:49 PM  b6 Allen-Gifford, Patrice (NIH/OD) [E] b6    Wooldridge, Shannon (NIH/OD) [E]  ; Pollock, Rachel (NIH/OD) [E] b6  ; Melencio, Chery  ing your ACTIV Participation Public	
Subject: RE: To Can we remo  From: Collins Sent: Thursdator To: Myles, Re b6  Cc: Parker, As Subject: RE: To Yes, please series	Francis (NIH/OD) ay, May 14, 2020 10 anate (NIH/OD) [E] shley (NIH/OD) [E] fime sensitive: Makesend an update in	ing your ACTIV Participation Public  n't think we need their permissions, right?  [E] b6  D:49 PM  b6 Allen-Gifford, Patrice (NIH/OD) [E] b6    Wooldridge, Shannon (NIH/OD) [E]  ; Pollock, Rachel (NIH/OD) [E] b6  ; Melencio, Chery  ing your ACTIV Participation Public	
Subject: RE: To Can we remo  From: Collins Sent: Thursdato: Myles, Re b6 Cc: Parker, As  Subject: RE: To Yes, please sethe tardy on FC	Francis (NIH/OD) ay, May 14, 2020 10 enate (NIH/OD) [E] shley (NIH/OD) [E] fime sensitive: Makesend an update in nes.	ing your ACTIV Participation Public  n't think we need their permissions, right?  [E] b6  D:49 PM  b6 ; Allen-Gifford, Patrice (NIH/OD) [E] b6  Wooldridge, Shannon (NIH/OD) [E]  ; Pollock, Rachel (NIH/OD) [E] b6  ; Melencio, Chery  ling your ACTIV Participation Public  the AM. And then I will appreciate a concatenated set of e-mail ad	
Subject: RE: To Can we remo  From: Collins Sent: Thursdato: Myles, Re b6 Cc: Parker, As Subject: RE: To Yes, please sthe tardy on FC  From: Myles,	Francis (NIH/OD)  And the NIHers? I do  Francis (NIH/OD)  And the NIHOD)  Francis (NIH/OD)   ing your ACTIV Participation Public  n't think we need their permissions, right?  [E] b6  0:49 PM  b6 ; Allen-Gifford, Patrice (NIH/OD) [E] b6  b6   Wooldridge, Shannon (NIH/OD) [E]; Pollock, Rachel (NIH/OD) [E]   b6  ; Melencio, Cherying your ACTIV Participation Public  the AM. And then I will appreciate a concatenated set of e-mail ad		
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By my count, we are still awaiting 39 responses, including 10 from NIH staff (highlighted in yellow). I don't think we really need to get permission from the NIHers, do we?

We gave folks until noon tomorrow, but you may want to send another email out in the morning to the non-NIH folks. I can give you an updated count in the morning.

### William Pao, M.D., Ph.D.

Head of Pharma Research and Early Development (pRED) Roche

### Annaliesa Anderson, Ph.D., FAAM

Vice President and Chief Scientific Officer, Bacterial Vaccines Pfizer

## Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

### Marc Charette, Ph.D.

Program Director
Division of Cardiovascular Diseases
National Heart, Lung, and Blood Institute, NIH

# Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration

#### Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader RTI International

#### Jay Grobler, Ph.D.

Director, Infectious Disease Biology Merck & Co., Inc.

### Judith Hewitt, Ph.D.

Deputy Director, Office of Biodefense, Research Resources and Translational Research National Institute of Allergy and Infectious Diseases, NIH

#### Samantha Jonson, M.P.S.

Special Assistant to the Director National Center for Advancing Translational Sciences, NIH

### Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center The Jackson Laboratory

### Elizabeth Ottinger, Ph.D.

Senior Program Manager, Division of Preclinical Innovation National Center for Advancing Translational Sciences, NIH

#### David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit GlaxoSmithKline

### Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences United States Army Medical Research Institute of Infectious Diseases

### Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform Sanofi

## Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology Director and Chief Academic Officer Tulane University National Primate Research Center

## Frank Stegmeier, Ph.D.

Chief Scientific Officer KSQ Therapeutics

## John Young, Ph.D.

Global Head Infectious Diseases and Vice President Roche

### Sylva Collins, Ph.D.

Director, Office of Biostatistics U.S. Food and Drug Administration

### Judith Currier, M.D.

Professor of Medicine University of California Los Angeles Division of Infectious Diseases Chair, AIDS Clinical Trial Group (ACTG)

### John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases Center for Drug Evaluation and Research U.S. Food and Drug Administration

#### Elliot Levy, M.D.

Senior Vice President, Global Development Amgen

### Naimish Patel, M.D.

Head of Global Development, Immunology and Inflammation Therapeutic Area Sanofi Genzyme

### Yves Rosenberg, M.D., MPH

Branch Chief, Atherothrombosis and Coronary Artery Disease Branch National Heart, Lung, and Blood Institute, NIH

#### Peter Stein, M.D.

Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration

#### Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi

### Jim Doroshow, M.D.

Director, Division of Cancer Treatment and Diagnosis National Cancer Institute, NIH

## Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs Eli Lilly and Company

### Seema Nayak, M.D.

Director, Office of Clinical Research Resources National Institute of Allergy and Infectious Diseases, NIH

## Manizhe Payton, MPH

Director, Office of Clinical Site Oversight, DAIDS National Institute of Allergy and Infectious Diseases, NIH

### Christine Sizemore, Ph.D.

Director, Division of International Relations Fogarty International Center, NIH

#### Peter Stein, M.D.

Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration

## Beth Bell, M.D., MPH

Clinical Professor, Global Health University of Washington

## Emilio Emini, Ph.D.

Director, TB & HIV Program
Bill & Melinda Gates Foundation

### Emmanuel Hanon, Ph.D.

Senior Vice President of Vaccines Research and Development GlaxoSmithKline

# Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development Pfizer

## Antonio Lanzavecchia, M.D.

Senior Vice President and Senior Research Fellow

Vir Biotechnology, Inc.

Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

### John Mascola, M.D.

Director, Dale and Betty Bumpers Vaccine Research Center National Institute of Allergy and Infectious Diseases, NIH

### Nancy Messonnier, M.D.

Director, Center for the National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention

### Jonathan Seals, Ph.D.

Director, Strategic Science and Technology Biomedical Advanced Research and Development Authority

From: Allen-Gifford, Patrice (NIH/OD) [E]		b6			
<b>Sent:</b> Thursday, May 14, 2020 1:27 PM					
To: Colline Francis (NILL (OD) [E]					
Cc: Myles, Renate (NIH/OD) [E]	<b>b6</b>	Parker, Ash	ley (NIH/OD) [E]	b6	
Wooldridge, Shannon (NIH/OD) [E]	b6		Pollock, Rachel (N	IIH/OD) [E]	··!
b6					
Subject: RE: Time sensitive: Making your	ACTIV Partio	cipation Public			
Certainly. We will put the responses in a s	ubfolder in	nmediately.			
From: Collins, Francis (NIH/OD) [E]	b6				
<b>Sent:</b> Thursday, May 14, 2020 1:03 PM					
<b>To:</b> Allen-Gifford, Patrice (NIH/OD) [E]		b6			
Cc: Myles, Renate (NIH/OD) [E]	b6	; Parker, Ash	ley (NIH/OD) [E]	<b>b6</b>	
Subject: FW: Time sensitive: Making your	ACTIV Part	icipation Public	C		
<del>-</del> 1		· · ·			11. 6.1
These are great responses, but my inb		flowing. Can y	ou set up a separa	ate file to put	all of the
responses that have this same subject	line?				
From: Bozzette, Sam (NIH/NCATS) [E]	b6				
<b>Sent:</b> Thursday, May 14, 2020 11:09 AM					
To: Collins Francis (NIH/OD) [F]	- C				
Cc: Myles, Renate (NIH/OD) [E]	<b>06</b>	Meltzer, Ab	bey (FNIH) [T]	b6	; Wholley, David
(FNIH) [T] <b>b6</b>		i	C		
Subject: RE: Time sensitive: Making your	ACTIV Partio	cipation Public			
I would be pleased to be listed under Their	rapeutics-C	linical WG:			
Sam Bozzette, MD, PhD					
CMO, NCATS					

Thank you

From: Collins, Francis (NIH/OD) [E] <b>b6</b>	
Sent: Thursday, May 14, 2020 11:00 AM	
To: Collins, Francis (NIH/OD) [E] <b>b6</b>	
Cc: Myles, Renate (NIH/OD) [E]	Meltzer, Abbey (FNIH) [T] <b>b6</b> ; Wholley, David
(FNIH) [T] <b>b6</b>	
Subject: Time sensitive: Making your ACTIV Particip	ation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

From:	Adam, Stacey (FN	,					
	(FYDIBOHF23SPDI	.T)/CN=RECIP	ients/cn=dci	0875F067964885	9E1CF101C0943	414-ADAMSJ4]	
Sent:	5/15/2020 3:19:3	3 AM					
То:	Eric Hughes	b6	; Rea	d, Sarah (NIH/NIA	AID) [E] [/o=Exch	angeLabs/ou=Exch	ange
	Administrative Gr	oup (FYDIBOH	F23SPDLT)/cn	=Recipients/cn=5	527b160038004a	199ae6e0bac2226	099-readsa];
	Ruxandra Draghia	-Akli	b6	Mellors, John	W [/o=Exchange	Labs/ou=Exchange	Administrative
	Group (FYDIBOHF	23SPDLT)/cn=	Recipients/cn	=user257cb364];	Naimish Patel	b6	Colvis,
	Christine (NIH/NC	ATS) [E] [/o=E	xchangeLabs/	ou=Exchange Adr	ministrative Gröu	ip	
	(FYDIBOHF23SPDI	T)/cn=Recipie	ents/cn=4b7e8	4cce098457896k	2df19fa172c87-	ccolvis]; Young, Joh	ın
	b6	]; s	tein, Peter (FD	A/CDER) [/o=Exc	:hangeLabs/ou=E	xchange Administr	ative Group
	(FYDIBOHF23SPDI	T)/cn=Recipie	ents/cn=b4a14	118481b4b39ba	7e62a8d6425f79	-Peter.Stein]; Pool	e, Mike
	be	3	; Buchmar	i, Tim (OS/ASPR/I	BARDA) (CTR) [/d	=ExchangeLabs/ou	=Exchange
	Administrative Gr	oup (FYDIBOF	lF23SPDLT)/cn	=Recipients/cn=0	00f8a853d8d740	f8a8cdd55cbf8eb9	da-Tim.Buchman];
	Vincent, Michael		b6	; Keith Gotteso	liener	b6	; Elliott Levy
	b6	; Wung, P	eter /US	b6	; Koroshetz,	Walter (NIH/NIND	S) [E]
	[/o=ExchangeLabs	ou=Exchang	e Administrati	ve Group			
	(FYDIBOHF23SPDI	.T)/cn=Recipie	ents/cn=e8338	dd7cdcd432e986	6961f1548c5ec6-	koroshetzw]; Higgs	s, Elizabeth
	(NIH/NIAID) [E] [/d	o=ExchangeLa	abs/ou=Exchan	ge Administrativ	e Group		
	(FYDIBOHF23SPDI	.T)/cn=Recipie	ents/cn=0601c	a55a82841aba16	6353b96cff8ca9-6	ehiggs]; Carlos O G	arner
	b6	G	off, David (NIH	/NHLBI) [E] [/o=E	xchangeLabs/ou	=Exchange Admini	strative Group
	(FYDIBOHF23SPDI	T)/cn=Recipie	ents/cn=03611	.3c7be0f42f897d	1294cfbb99c10-ք	goffdc]	
CC:	Elizabeth Kim [elk	im@deloitte.d	com]; Menetsk	ki, Joseph (FNIH)	[T] [/o=Exchange	Labs/ou=Exchange	Administrative
	Group (FYDIBOHF	23SPDLT)/cn=	Recipients/cn	=5001af52dc4a42	27ea3d34f1e072	f8cb7-menetskijp];	Alvarez, Rosa
	Maria [rosalvarez	@deloitte.con	n]; Parker, Ash	ley (NIH/OD) [E]	[/o=ExchangeLak	os/ou=Exchange Ad	lministrative Group
	(FYDIBOHF23SPDI	.T)/cn=Recipie	ents/cn=306b2	244466140faa95	aaaafe06ebd70-	parkeras]; Wholley	, David (FNIH) [T]
	[/o=ExchangeLabs	ou=Exchang	e Administrati	ve Group			
	(FYDIBOHF23SPDL	.T)/cn=Recipie	ents/cn=cd9e7	02fcf28414883d0	0b6996d677257-	wholleyd]; Rose Li	Central Account
	[FNIH@roseliasso	•					
Subject:	Initial Follow-up to	ACTIV TX-Cli	inical Agent Pr	ioritization Subgr	oup #10		
Attachments:	Therapeutic inform	nation reques	st form-v6.doc	x; ACTIV_Therape	eutics-Clinical_A <mark>l</mark>	P Sub-Group Meeti	ng
	14May2020_Key	Takeaways.pd	f; ACTIV_Thera	apeutics Clinical A	Agent Prioritization	on Scoring Guide_v	3.pptx

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Please find attached the follow up materials from today's meeting.

### The materials include:

- 1. A quick capture of action items and major decisions from the meeting. A formal summary will follow tomorrow.
- 2. Updated Agent Prioritization Criteria Slides with the changes suggested today made. Please review for final approval.
- 3. An updated version of the company survey/RFI that we would use for multiple purposes: 1) to do specific information solicitation on high priority compounds that this group wishes to score, 2) to have any company or group who has submitted an agent for your consideration populate this so we are working on the right data, and 3) potentially to do a broad company solicitation of additional compounds that the companies would like to have considered for testing.

Please review and let us know if this reflects the changes suggested and that it has all the questions you would want to see to ensure that we will have the right data to review for our high priority compounds. We have worked to balance being thorough with making sure it is not too onerous for a company to fill out. Please let us know if you have any amendments or additions.

Thank you for your review of these materials.

Thanks,

### Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: **b6** | Mobile: **b6** 

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



То:	Whalley Devid (FNU) [T] [/a Fyshangelaha/ay Fyshange Administrative Copyr
	Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC:	Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
Subject:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc] RE: Meeting notes from yesterday's ACTIV EC meeting
Jubject.	KL. Weeting notes from yesterday's ACTIV to meeting
I think it's	OK, but given the way in which the previous distributions ended up in the hands of Jon Cohen, a
	minder to the WG members that these are confidential would be a good thing.
specific re	militides to the WO members that these are confidential would be a good thing.
FC	
	lley, David (FNIH) [T] <b>b6</b> day, May 14, 2020 11:35 PM
To: Collins.	Francis (NIH/OD) [F1] <b>h6</b>
Cc: Freire,	day, May 14, 2020 11:35 PM  Francis (NIH/OD) [E] b6  Varia (FNIH) [T] b6  V: Meeting notes from vesterday's ACTIV FC meeting
Subject: FV	V: Meeting notes from yesterday's ACTIV EC meeting
I don't see	any problem with this, do you? Each page is marked Confidential and Predecisional.
From: Ada	n, Stacey (FNIH) [T] <b>b6</b>
Sent: Thurs	day, May 14, 2020 10:54 PM y, David (FNIH) [T] <b>b6</b>
Subject: RE	: Meeting notes from yesterday's ACTIV EC meeting
-	
Hi David, Am I allow	ed to share the notes with my WG? They asked today if they would be shared since the group was discussing
Hi David, Am I allowe our letter.	
Hi David, Am I allowe our letter. Thanks,	
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Hi David, Am I allowe our letter. Thanks, Stacey Stacey Director, ( Research I Direct: From: Who	Adam, PhD Cancer Cartnerships  b6    Mobile: b6    Mobile: b6    Mobile: b6    Mobile: b6    day, May 14, 2020 10:50 PM
Hi David, Am I allowed our letter. Thanks, Stacey Stacey Director, C Research I Direct: From: Who Sent: Thurs	Adam, PhD  Cancer Cartnerships  b6    Mobile: b6   b6   day, May 14, 2020 10:5UPIV   Francis (NIH/OD) [E] b6 ; Dolsten, Mikael b6 ; Fauci, Anthony
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Hi David, Am I allowe our letter. Thanks, Stacey Stacey Director, ( Research I Direct: From: Who Sent: Thurs To: Collins, (NIH/NIAID	Adam, PhD Tancer Tartnerships  b6  Mobile:  b6  Mobile:  b6  Molicy, David (FNIH) [T]
Hi David, Am I allowed our letter. Thanks, Stacey Stacey J. A. Director, ( Research I Direct: From: Who Sent: Thurs To: Collins, (NIH/NIAID) Cc: Colvis, (Vine Collins)	Adam, PhD  Gancer Partnerships B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B7  Mobile:
Hi David, Am I allowe our letter. Thanks, Stacey Stacey Director, ( Research I Direct:  From: Who Sent: Thurs To: Collins, (NIH/NIAID Cc: Colvis, 6 Hughes, Er	Adam, PhD  Gancer Partnerships B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B6  Mobile: B7  Mobile:
Hi David, Am I allowe our letter. Thanks, Stacey Stacey J. And Director, (Research I Direct: Thursto: Collins, (NIH/NIAID) Cc: Colvis, Hughes, Er	Adam, PhD  ancer Partnerships b6    Mobile:   b6

Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]

From:

	b6	; Austin, Christopher (NIH/NCA	TS) [E] {	b <b>6</b>	; Lane, C	liff (NIH/N	IAID) [E]
1	b6	>; Parker, Ashley (NIH/OD) [E]	b6	! '	, Lawrence (NI	. ,	
	b6	; Wolinetz, Carrie (NIH/OD) [E]			1		
ſ		>; Alvarez, Rosa < <u>rosalvarez@deloitte.com</u>					
_	Elsaid, Olivia < oels	aid@deloitte.com>; Gonzalez, Nina <ning< th=""><th></th><th></th><th></th><th>nie (FNIH)</th><th>[T]</th></ning<>				nie (FNIH)	[T]
	b6	; Kim, Elizabeth < <u>elkim@deloitte.com</u> >; I				6	; Santos,
		b6 ; Stratton, Ben <bstr< th=""><th>atton@deloitte</th><th>e.com&gt;; To</th><th>olman, Brett</th><th></th><th>•</th></bstr<>	atton@deloitte	e.com>; To	olman, Brett		•
		<u>te.com</u> >; Tountas, Karen (FNIH) [T]	<b>b6</b>	Wachtel,	Jonathan		
		te.com>; Wholley, David (FNIH) [T]	<b>ס</b> ט				
	Subject: Meeting	notes from yesterday's ACTIV EC meeting					

Dear ACTIV Executive Committee Members, Working Group Co-Chairs and guest participants:

Here are the complete notes, including action items, from yesterday's ACTIV EC meeting. Please let me know if there is anything we may have missed. In addition, I am forwarding at Janet Woodcock's request slides she mentioned describing the global landscape of studies on convalescent plasma and hyperimmune globulin.

I look forward to continued discussions on our next EC call, scheduled for next Wednesday, May 20.

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]

**Sent**: 5/15/2020 9:02:26 AM

To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]

**Subject**: FW: Time sensitive: Making your ACTIV Participation Public

From: Emmanuel Hanon b6
Sent: Friday, May 15, 2020 2:32 AM
To: Collins, Francis (NIH/OD) [E] b6

Subject: Re: Time sensitive: Making your ACTIV Participation Public

Ok for me

R M

From: "Collins, Francis (NIH/OD) [E]" b6

Date: Thursday, 14 May 2020 at 17:00

To: "Collins, Francis (NIH/OD) [E]" b6

"Meltzer, Abbey (FNIH) [T]" b6

"Wholley, David (FNIH) [T]" b6

Subject: Time sensitive: Making your ACTIV Participation Public

### **EXTERNAL**

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

Francis S. Collins, MD, PhD NIH Director

GSK monitors email communications sent to and from GSK in order to protect GSK, our employees, customers, suppliers and business partners, from cyber threats and loss of GSK Information. GSK monitoring



Sent: 5/15/2020 11:49:33 AM Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr] CC: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd] Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information Attachments: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups These list were compiled yesterday morning by FNIH without any names, only emails. I wanted to double check the emails FNIH provided with names of the reps on the 4 ACTIV WGs along with the reps who participated in the April 3rd PPP meeting. I found 8 emails that were missing and shared this with FC yesterday afternoon. Andy Plump was among the 8 which explains why the email was missing. From: Myles, Renate (NIH/OD) [E] **Sent:** Thursday, April 16, 2020 8:15 AM To: Parker, Ashley (NIH/OD) [E] b6 Cc: Wolinetz, Carrie (NIH/OD) [E Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information I used the master list that you sent to him earlier in the week and Takeda wasn't in there. I never received an updated version of the master list. b6 From: Parker, Ashley (NIH/OD) [E] Sent: Thursday, April 16, 2020 8:14 AM To: Myles, Renate (NIH/OD) [E] **b6** Cc: Wolinetz, Carrie (NIH/OD) [E Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information Here is the updated list – seems FC used your emails and not the master list. From: Myles, Renate (NIH/OD) [E] { Sent: Thursday, April 16, 2020 8:10 AM To: Parker, Ashley (NIH/OD) [E] Cc: Wolinetz, Carrie (NIH/OD) [ Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information I pulled the names from the attached that you sent earlier in the week. There isn't a Takeda contact on this list. Would vou send it to me? From: Parker, Ashley (NIH/OD) [E] **b6** Sent: Thursday, April 16, 2020 8:03 AM

**b**6

Subject: RE: PLEASE READ: Draft Email to Collect Communication Contact Information

Good morning Renate,

To: Myles, Renate (NIH/OD) [E]

Cc: Wolinetz, Carrie (NIH/OD) [E

Our rep at Takeda, Andy Plump is included on the master list. I am confirming with Francis that he used our master list for his email that went out last night - I should be able to confirm this for you this morning. I hope you are staying safe and healthy; maybe even getting some rest in between the constant COVID activities. Thanks, Ashley From: Myles, Renate (NIH/OD) [E] **b6** Sent: Thursday, April 16, 2020 7:14 AM To: Parker, Ashley (NIH/OD) [E] **b6** Cc: Wolinetz, Carrie (NIH/OD) [ Subject: FW: PLEASE READ: Draft Email to Collect Communication Contact Information Importance: High Hi Ashley: I'm not sure if Francis added a Takeda contact to his email. I could not find one on the master contact list. I have not heard from their organizations yet. Would you let me know if you provided that to him last night or if they are missing from this email? Need to send it to this group this morning. Thanks, Renate From: Myles, Renate (NIH/OD) [E] Sent: Wednesday, April 15, 2020 9:11 PM To: Collins, Francis (NIH/OD) [E] Cc: Wood, Gretchen (NIH/OD) [E McManus, Ayanna (NIH/OD) [E] b6 ; Parker, Burklow, John (NIH/OD) [E] b6 Ashley (NIH/OD) [E] b6 Subject: PLEASE READ: Draft Email to Collect Communication Contact Information Importance: High Hi Francis: We need to collect the communication contacts from the partner organizations so we can share the release with them for review. Below is 1) a draft email for you to send to the company participants, 2) the contacts for the companies we list in the release except for Takeda (I could not find a Takeda contact on the master list; hoping Ashley can provide); 3) those who should be copied (feel free to add others). Dear ACTIV colleagues: As I mentioned earlier today, we would like to announce the plans for a public-private partnership as expeditiously as possible. Please provide the name of the most appropriate communication contact from your company so that we may share a draft of the embargoed press release for your review. Please send the contact information to Renate Myles at b6 this evening, if possible. and Abbey Meltzer BCC:

	<b>b6</b>	
CC:		
	b6	
Thanks.		

Renate

From: Pollock, Rachel (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4887CB3513E242DFA7D2DF712DCC6D6A-POLLOCKRC]

Sent: 5/15/2020 12:08:18 PM

To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]

CC: Allen-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]; Parker, Ashley (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wooldridge, Shannon

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]

Subject: RE: Time sensitive: Making your ACTIV Participation Public Attachments: Time sensitive: Making your ACTIV Participation Public

Renate - in case it is helpful, attached is what I believe to be the send round email, and which includes the full list of email addresses in the bcc line. CC'ing Ashley to confirm.

0:	b6
C:	b6

From: Myles, Renate (NIH/OD) [E]	b6		
<b>Sent:</b> Friday, May 15, 2020 7:53 AM			
To: Collins, Francis (NIH/OD) [E]	b6		
Cc: Allen-Gifford, Patrice (NIH/OD) [E]	b6	; Parker, Ashley (NIH/OD	) [E]
<b>b6</b> ; Wooldridge,	Shannon (NIH/OD) [E]	b6	Pollock, Rachel (NIH/OD
[E] <b>b6</b>			
Subject: FW: Time sensitive: Making vo	ur ACTIV Participation Publi	ic	

**Subject:** FW: Time sensitive: Making your ACTIV Participation Public

Hi Francis:

Below is the list of 23 vpeople who have not yet responded to your email. I cross referenced these names with the email list that Ashely sent and pulled addresses from that list. I didn't find emails for a number of these people, but I know there was a second round that went out using emails I don't have. Hoping Ashley can provide the missing emails.

### Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

### Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration

### Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader RTI International

### Jay Grobler, Ph.D.

Director, Infectious Disease Biology Merck & Co., Inc.

### Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center The Jackson Laboratory

### David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit GlaxoSmithKline

### Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences United States Army Medical Research Institute of Infectious Diseases

### Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform Sanofi

### Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology Director and Chief Academic Officer Tulane University National Primate Research Center

### Frank Stegmeier, Ph.D.

Chief Scientific Officer KSQ Therapeutics

### Sylva Collins, Ph.D.

Director, Office of Biostatistics U.S. Food and Drug Administration

### Judith Currier, M.D.

Professor of Medicine University of California Los Angeles Division of Infectious Diseases Chair, AIDS Clinical Trial Group (ACTG)

### b6

### John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases Center for Drug Evaluation and Research U.S. Food and Drug Administration

### b6

### Elliot Levy, M.D.

Senior Vice President, Global Development

Amgen

**b6** 

Lionel Bascles, Ph.D. Senior Vice President, Global Head of Clinical Sciences & Operations
Sanofi
b6
Carlos Garner, Ph.D.
Vice President, Global Regulatory Affairs
Eli Lilly and Company
b6
<u> </u>
Peter Stein, M.D.
Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
<b>b6</b>
Beth Bell, M.D., MPH
Clinical Professor, Global Health
University of Washington
Emilio Emini, Ph.D.
Director, TB & HIV Program
Bill & Melinda Gates Foundation
personal resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonance resonan
b6
Kathrin Jansen, Ph.D.
Senior Vice President and Head of Vaccine Research and Development
Pfizer
<u>                                     </u>
b6
Antonio Lanzavecchia, M.D.
Senior Vice President and Senior Research Fellow
Vir Biotechnology, Inc.
Director, Institute for Research in Biomedicine, Bellinzona, Switzerland
<b>b6</b>
Nancy Messonnier, M.D.
Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
b6
Jonathan Seals, Ph.D.
Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority
biomedical Advanced Research and Development Additiontly
From: Collins, Francis (NIH/OD) [E] <b>b6</b>
<b>Sent:</b> Thursday, May 14, 2020 11:00 AM
To: Collins, Francis (NIH/OD) [E]
Cc: Myles, Renate (NIH/OD) [E]
(FNIH) [T] <b>b6</b>
Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS] Sent: 5/15/2020 12:16:23 PM To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr] CC: Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]; Allen-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]; Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense] Subject: Re: Time sensitive: Making your ACTIV Participation Public Renate, we are adding the emails you do not have — these were sent later on yesterday. Ashley Parker, Ph.D. Special Assistant to Acting Chief of Staff to the NIH Director Office of the Director | National Institutes of Health b6 On May 15, 2020, at 8:13 AM, Myles, Renate (NIH/OD) [E] wrote: Thanks, Rachel. Jay Grobler just responded, so I've removed him from the list. Will you be sending it out this morning? From: Pollock, Rachel (NIH/OD) [E] **b6** Sent: Friday, May 15, 2020 8:08 AM To: Myles, Renate (NIH/OD) [E] Cc: Allen-Gifford, Patrice (NIH/OD) [E] Parker, Ashley (NIH/OD) [E] ; Wooldridge, Shannon (NIH/OD) [E] b6 b6 Subject: RE: Time sensitive: Making your ACTIV Participation Public Renate - in case it is helpful, attached is what I believe to be the send round email, and which includes the full list of email addresses in the bcc line. CC'ing Ashley to confirm. Rachel Pollock O: 301.827.8362 b6 From: Myles, Renate (NIH/OD) [E] **Sent:** Friday, May 15, 2020 7:53 AM To: Collins, Francis (NIH/OD) [E] Cc: Allen-Gifford, Patrice (NIH/OD) [E] Parker, Ashley (NIH/OD) [E] ; Wooldridge, Shannon (NIH/OD) [E ; Pollock, b6 Rachel (NIH/OD) [E Subject: FW: Time sensitive: Making your ACTIV Participation Public Hi Francis:

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### Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

### Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration

### Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader RTI International

### Jay Grobler, Ph.D.

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### Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences United States Army Medical Research Institute of Infectious Diseases

### Srinivas Rao, DVM, Ph.D.

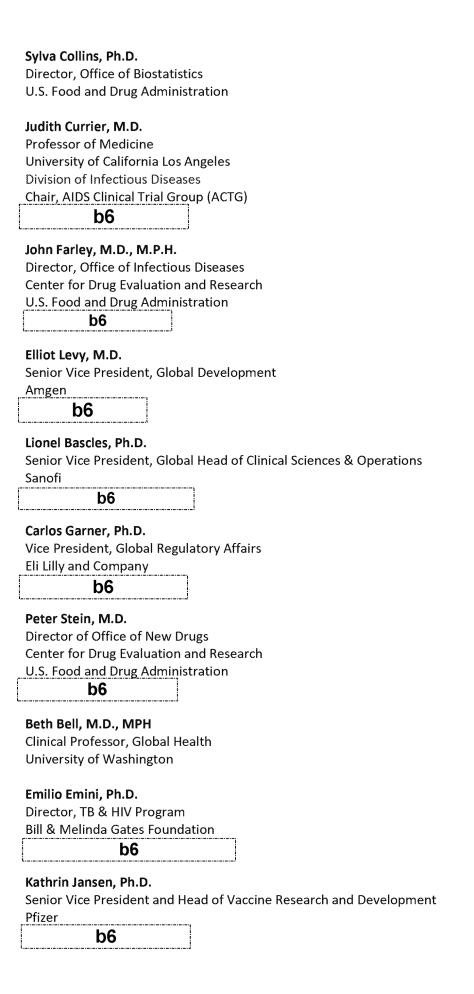
Global Head, Translational In Vivo Models Global Research Platform Sanofi

### Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology Director and Chief Academic Officer Tulane University National Primate Research Center

### Frank Stegmeier, Ph.D.

Chief Scientific Officer KSQ Therapeutics



# Antonio Lanzavecchia, M.D. Senior Vice President and Senior Research Fellow Vir Biotechnology, Inc. Director, Institute for Research in Biomedicine, Bellinzona, Switzerland b6 Nancy Messonnier, M.D. Director, Center for the National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention b6 Jonathan Seals, Ph.D. Director, Strategic Science and Technology Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD) [E] b6

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E] b6

Cc: Myles, Renate (NIH/OD) [E] b6

Wholley, David (FNIH) [T] b6

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

From:	Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]		
Sent:	5/15/2020 12:29:37 PM		
То:	Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group		
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]		
Subject:	RE: Time sensitive: Making your ACTIV Participation Public		
Thanks!!			
From: Br	odd, Lauren (NIH/OD) [E] <b>b6</b>		
Sent: Frid	day, May 15, 2020 8:21 AM		
To: Parke	er, Ashley (NIH/OD) [E] <b>b6</b>		
Subject:	RE: Time sensitive: Making your ACTIV Participation Public		
Hi Ashley	/,		
See list b	elow with emails added. Let me know if you need anything else.		
Thanks,			
Lauren			
Sent: Frid To: Brode	hrker, Ashley (NIH/OD) [E] <b>b6</b> day, May 15, 2020 8:08 AM d, Lauren (NIH/OD) [E] <b>b6</b> Re: Time sensitive: Making your ACTIV Participation Public		
Thanks, l	Lauren!		
Achlou D	arker Ph D		
-	arker, Ph.D. Assistant to Acting Chief of Staff to the NIH Director		
	the Director   National Institutes of Health		
Tel			
\\\	<u>b6</u>		
On May :	15, 2020, at 8:07 AM, Brodd, Lauren (NIH/OD) [E] <b>b6</b> wrote:		
•	Sure I'll look on your excel sheets for these emails.		
-	suite in look on your excersineets for these emails.		
	From: Parker, Ashley (NIH/OD) [E] <b>b6</b>		
	Sent: Friday, May 15, 2020 8:04 AM		
	Fo: Brodd, Lauren (NIH/OD) [E] <b>b6</b>		
	Subject: Re: Time sensitive: Making your ACTIV Participation Public		
ŀ	Hi Lauren,		
	Can you help by adding the missing emails to the folks names below? I would assume this is already done in the revised document?		

Thanks Ashley	,
Special	Parker, Ph.D. Assistant to Acting Chief of Staff to the NIH Director of the Director   National Institutes of Health b6
Begin f	orwarded message:
	From: "Myles, Renate (NIH/OD) [E]" <b>b6</b> Date: May 15, 2020 at 7:52:35 AM EDT  To: "Collins, Francis (NIH/OD) [E]" <b>b6</b> Cc: "Allen-Gifford, Patrice (NIH/OD) [E]" <b>b6</b> "Parker, Ashley
	(NIH/OD) [E]" \ b6
	Subject: FW: Time sensitive: Making your ACTIV Participation Public
	Hi Francis:
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	b6
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	Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health  6
	Damon Deming, Ph.D. Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration  b6
Ī	Greg Gatto, Ph.D.  Drug Development Regulatory Project Leader  RTI International  b6
	Jay Grobler, Ph.D.  Director, Infectious Disease Biology

Merck & Co., Inc.

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Cat Lutz, Ph.D.	
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Center	and orphan biscuse
The Jackson Laboratory	
b6	
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GlaxoSmithKline	
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<u></u>	
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b6

From: Collins, Francis (NIH/OD) [E]	b6	
Sent: Thursday, May 14, 2020 11:00 AM		
To: Collins, Francis (NIH/OD) [E]	h6	
Cc: Myles, Renate (NIH/OD) [E]	b6	, Meltzer, Abbey (FNIH) [T]
b6 ; Wholley, David (FN	VIH) [T]	b6
Subject: Time sensitive: Making your ACT	ΓΙV Partici	pation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

**Sent**: 5/15/2020 12:57:02 PM

To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Collins, Francis (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

CC: Allen-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]; Wooldridge, Shannon

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]; Pollock, Rachel (NIH/OD)

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]

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<b>Sent:</b> Friday, May 15, 2020 7:53 AM
To: Collins, Francis (NIH/OD) [E] b6
Cc: Allen-Gifford, Patrice (NIH/OD) [E] b6 ; Parker, Ashley (NIH/OD) [E]
b6 ; Wooldridge, Shannon (NIH/OD) [E] b6 ; Pollock, Rachel (NIH/OD)
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Cc: Myles, Renate (NIH/OD) [E] <b>b6</b>	Meltzer, Abbey (FNIH) [T]	b6	Wholley, David
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(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]

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Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

**Sent**: 5/15/2020 1:44:15 PM

To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]

**Subject**: FW: Time sensitive: Making your ACTIV Participation Public **Attachments**: Leadership _ National Institutes of Health (NIH).pdf

Hi Lauren,

One things that would be helpful – can we cross check the updated list Renate shared with the attached spreadsheet of emails

From: Myles, Renate (NIH/OD) [E]	b6				
<b>Sent:</b> Friday, May 15, 2020 9:21 AM			ļ <del></del>		
To: Parker, Ashley (NIH/OD) [E]	b6	; Collins	, Francis (NIH/OD) [E]	b6	
Cc: Allen-Gifford, Patrice (NIH/OD) [E]		b6	; Wooldridge, Shanr	non (NIH/OD) [I	E]
b6 →; Pollo	ck, Rachel (NI	IH/OD) [E]	b6		
Subject: RE: Time sensitive: Making vou	ur ACTIV Parti	icipation Pub	lic		

Hi Ashley:

Attached is the full list of members currently listed on the website in staging. I received the list from FNIH communications. Please let me know of any changes.

Thanks, Renate

From: Parker, Ashley (NIH/OD) [E]	<b>b6</b>					
Sent: Friday, May 15, 2020 9:11 AM			-			
To: Myles, Renate (NIH/OD) [E]	b6	; Collins	, Francis (NIH/OD) [E]	b	)6 	
Cc: Allen-Gifford, Patrice (NIH/OD) [	E]	b6	; Wooldridge, S	hannon (N	NIH/OD) [E]	
<b>b6</b> ; Pc	ollock, Rachel (N	IH/OD) [E]	b6			
Subject: RE: Time sensitive: Making	your ACTIV Part	cicipation Pu	blic			

Hi Renate,

I've added the emails below but we have a major version control issues. I've been working with Cheryl to receive updates and did not have Sylvia Collins, Beth Bell and Jonathan Seals and apparently they are listed on a separate list the FNIH communications team is tracking.

We can send follow up emails to everyone except for those three - they will need to be contacted.

Moving forward, it may be best for you to receive updates from the communications team – FNIH is managing multiple spreadsheets one for the emails Cheryl is managing to schedule meetings and a separate list for the communications office.

# Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology

<u>University of North Car</u>olina, Gillings School of Global Public Health **b6** 

Damon Deming, Ph.D.
Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration
<b>b6</b>
<u>Landanianianianianianianianianianianianiania</u>
Greg Gatto, Ph.D.
Drug Development Regulatory Project Leader
RTI International
b6
Jay Grobler, Ph.D.
Director, Infectious Disease Biology
Merck & Co., Inc.
<u>b6</u>
Cat Luta Dh D
Cat Lutz, Ph.D.
Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center
The Jackson Laboratory
<b>b6</b>
David Payne, Ph.D.
Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline
<u>b6</u>
Louise Pitt, Ph.D.
Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases
<b>b6</b>
<u>L</u>
Srinivas Rao, DVM, Ph.D.
Global Head, Translational In Vivo Models Global Research Platform
Sanofi
b6
Jay Rappaport, Ph.D.
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Jay Rappaport, Ph.D. Professor of Microbiology and Immunology Director and Chief Academic Officer
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Judith Currier, M.D.

Professor of Medicine

University of California Los Angeles Division of Infectious Diseases
Chair, AIDS Clinical Trial Group (ACTG) <b>b6</b>
John Farley, M.D., M.P.H.  Director, Office of Infectious Diseases  Center for Drug Evaluation and Research  U.S. Food and Drug Administration
b6
Elliot Levy, M.D. Senior Vice President, Global Development Amgen  b6
Lionel Bascles, Ph.D. Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi
b6
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6
Peter Stein, M.D. Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration  b6
Beth Bell, M.D., MPH Clinical Professor, Global Health University of Washington  b6
Emilio Emini, Ph.D.
Director, TB & HIV Program  Bill & Melinda Gates Foundation  b6
<b>Kathrin Jansen, Ph.D.</b> Senior Vice President and Head of Vaccine Research and Development Pfizer
b6
Antonio Lanzavecchia, M.D. Senior Vice President and Senior Research Fellow Vir Biotechnology, Inc. Director, Institute for Research in Biomedicine, Bellinzona, Switzerland  66

# Nancy Messonnier, M.D. Director, Center for the National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention b6 Jonathan Seals, Ph.D. Director, Strategic Science and Technology Biomedical Advanced Research and Development Authority b6

From: Myles, Renate (NIH/OD) [E]	b6	-	
<b>Sent:</b> Friday, May 15, 2020 7:53 AM			
To: Collins, Francis (NIH/OD) [E]	b6		
Cc: Allen-Gifford, Patrice (NIH/OD) [E]	b6	; Parker, Ashley (NIH/OD	) [E]
b6 Wooldridge	e, Shannon (NIH/OD) [	[E] <b>b6</b>	Pollock, Rachel (NIH/OD)
[E] <b>b6</b>		i	
Subject: FW: Time sensitive: Making y	our ACTIV Participatio	on Public	

Hi Francis:

Below is the list of 23 vpeople who have not yet responded to your email. I cross referenced these names with the email list that Ashely sent and pulled addresses from that list. I didn't find emails for a number of these people, but I know there was a second round that went out using emails I don't have. Hoping Ashley can provide the missing emails.

# **b6**

#### Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

# Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration

# Greg Gatto, Ph.D.

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Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center The Jackson Laboratory

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Vice President & Head, Medicine Opportunities Research Unit GlaxoSmithKline

# Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences United States Army Medical Research Institute of Infectious Diseases

# Srinivas Rao, DVM, Ph.D.

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# Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology Director and Chief Academic Officer Tulane University National Primate Research Center

# Frank Stegmeier, Ph.D.

Chief Scientific Officer KSQ Therapeutics

# Sylva Collins, Ph.D.

Director, Office of Biostatistics U.S. Food and Drug Administration

#### Judith Currier, M.D.

Professor of Medicine University of California Los Angeles Division of Infectious Diseases Chair, AIDS Clinical Trial Group (ACTG)

b6

# John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases Center for Drug Evaluation and Research U.S. Food and Drug Administration

**b6** 

# Elliot Levy, M.D.

Senior Vice President, Global Development

Amgen

b6

# Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi

**b6** 

# Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs Eli Lilly and Company garner_carlos_o@lilly.com

	Peter Stein, M.D.
	Director of Office of New Drugs
	Center for Drug Evaluation and Research
	U.S. Food and Drug Administration
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	Beth Bell, M.D., MPH
	Clinical Professor, Global Health
	University of Washington
	Emilio Emini, Ph.D.
	Director, TB & HIV Program
	Bill & Melinda Gates Foundation
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	Kathrin Jansen, Ph.D.
	Senior Vice President and Head of Vaccine Research and Development
	Pfizer
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į	NO I
	Antonia Languagehia, M.D.
	Antonio Lanzavecchia, M.D. Senior Vice President and Senior Research Fellow
	Vir Biotechnology, Inc.
	Director, Institute for Research in Biomedicine, Bellinzona, Switzerland
	<b>b6</b>
	Noney Magazamian BA D
	Nancy Messonnier, M.D.
	Director, Center for the National Center for Immunization and Respiratory Diseases
į	Centers for Disease Control and Prevention
	b6
	Jonathan Seals, Ph.D.
	Director, Strategic Science and Technology
	Biomedical Advanced Research and Development Authority
	From: Collins, Francis (NIH/OD) [E] <b>b6</b>
	<b>Sent:</b> Thursday, May 14, 2020 11:00 AM
	To: Collins, Francis (NIH/OD) [E]
	Cc: Myles, Renate (NIH/OD) [E]
	(FNIH) [T] <b>b6</b>
	Subject: Time sensitive: Making your ACTIV Participation Public
	Dear ACTIV Colleagues:
	Yes, this message is for you, though your address was in the bcc line!
	NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our

efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow,

Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

APAR0000017175

Thanks, Francis

Francis S. Collins, MD, PhD NIH Director

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD] Sent: 5/15/2020 1:47:20 PM To: Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Burgess, Timothy Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra b6 Eisner, Mark b6 Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Garner, Carl **b6** ; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Gottesdiener, Keith **b6** ; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Hughes, Eric ; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; LaVange, Lisa b6 ; Levy, Elliot b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep b6 Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish 
 b6
 Peppercorn, Amanda
 b6
 Poole, Mike

 b6
 Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Tenaerts, Pamela b6; Wung, Peter b6
Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group CC: (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Kim, Elizabeth [elkim@deloitte.com] Subject: ACTIV EC Meeting Notes from Wednesday

Dear ACTIV Therapeutics-Clinical Working Group members:

Attachments: 2020-05-13_Executive_Committee_Meeting_Summary 5-14-20 F (002).pdf

Please see attached the meeting notes and action items from the ACTIV Executive Committee teleconference held on May 13, the majority of which was focused on reviewing your letter to the Committee. I just sent them to the EC late last night and am happy to share with you. As noted the notes are marked confidential and predecisional; please treat with appropriate discretion and do not distribute further.

Thanks, David

David Wholley Senior Vice-President, Research Partnerships Foundation for the National Institutes of Health

b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS] Sent: 5/15/2020 2:27:11 PM To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr] CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm] Subject: RE: Time sensitive: Making your ACTIV Participation Public Leadership _ National Institutes of Health (NIH).pdf; 1-Draft_NIH_ACTIV_Webpage_Content 5.14.2020 w changes Attachments: updated editsLBAP.docx Hi Renate, Sparing FC's inbox and others. With many thanks to Lauren for helping us with this. Please see edits attached and below - the alphabetizing of the names can be ignored as this is updated in the revised version you've provided. A few minor edits: Co-chairs of the working groups should be identified Consistency with MD or M.D. Minor change to John Mellors Thanks, **Ashley** From: Myles, Renate (NIH/OD) [E] **Sent:** Friday, May 15, 2020 9:21 AM Collins, Francis (NIH/OD) [E] To: Parker, Ashley (NIH/OD) [E] b6 Cc: Allen-Gifford, Patrice (NIH/OD) [E][ 3 Wooldridge, Shannon (NIH/OD) [E] ; Pollock, Rachel (NIH/OD) [E] Subject: RE: Time sensitive: Making your ACTIV Participation Public Hi Ashley: Attached is the full list of members currently listed on the website in staging. I received the list from FNIH communications. Please let me know of any changes. Thanks, Renate From: Parker, Ashley (NIH/OD) [E] b6 Sent: Friday, May 15, 2020 9:11 AM Collins, Francis (NIH/OD) [E] To: Myles, Renate (NIH/OD) [E] b6 Cc: Allen-Gifford, Patrice (NIH/OD) [E] b6 ; Wooldridge, Shannon (NIH/OD) [E] ; Pollock, Rachel (NIH/OD) [E] b6

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# Ralph Baric, Ph.D. William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health b6 Damon Deming, Ph.D. Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration **b6** Greg Gatto, Ph.D. Drug Development Regulatory Project Leader **RTI International** b6 Jay Grobler, Ph.D. Director, Infectious Disease Biology Merck & Co., Inc. **b6** Cat Lutz, Ph.D. Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center The Jackson Laboratory b6 David Payne, Ph.D. Vice President & Head, Medicine Opportunities Research Unit GlaxoSmithKline b6 Louise Pitt, Ph.D. Director, Center for Aerobiological Sciences United States Army Medical Research Institute of Infectious Diseases b6 Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform

Sanofi

b6

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Professor of Microbiology and Immunology

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Professor of Medicine
University of California Los Angeles
Division of Infectious Diseases
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\
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Director, TB & HIV Program
Bill & Melinda Gates Foundation
b6
Kathrin Jansen, Ph.D. Senior Vice President and Head of Vaccine Research and Development Pfizer  b6  Antonio Lanzavecchia, M.D. Senior Vice President and Senior Research Fellow Vir Biotechnology, Inc. Director, Institute for Research in Biomedicine, Bellinzona, Switzerland b6  Nancy Messonnier, M.D. Director, Center for the National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention b6  Jonathan Seals, Ph.D. Director, Strategic Science and Technology Biomedical Advanced Research and Development Authority b6
From: Myles, Renate (NIH/OD) [E] b6  Sent: Friday, May 15, 2020 7:53 AM  To: Collins, Francis (NIH/OD) [E] b6  Cc: Allen-Gifford, Patrice (NIH/OD) [E] b6 ; Parker, Ashley (NIH/OD) [E]  b6   Wooldridge, Shannon (NIH/OD) [E] b6   Pollock, Rachel (NIH/OD)
Subject: FW: Time sensitive: Making your ACTIV Participation Public
Hi Francis:  Below is the list of 23 vpeople who have not yet responded to your email. I cross referenced these names with the email list that Ashely sent and pulled addresses from that list. I didn't find emails for a number of these people, but I know there was a second round that went out using emails I don't have. Hoping Ashley can provide the missing emails.
<b>b6</b>

# Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

## Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration

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Professor of Medicine University of California Los Angeles Division of Infectious Diseases Chair, AIDS Clinical Trial Group (ACTG)

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# John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases Center for Drug Evaluation and Research U.S. Food and Drug Administration

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Elliot Levy, M.D.
Senior Vice President, Global Development
Amgen
b6
Attack Book Loop Bloom
Lionel Bascles, Ph.D.
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b6
<u> </u>
Jonathan Seals, Ph.D.
Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD)	[E] <b>b6</b>			
Sent: Thursday, May 14, 2020 11	1:00 AM			
To: Collins, Francis (NIH/OD) [E]	L.C			
Cc: Myles, Renate (NIH/OD) [E]	<b>b6</b>	; Meltzer, Abbey (FNIH) [T]	b6	Wholley, David
(FNIH) [T] { <b>b6</b>		·		
Subject: Time sensitive: Making	your ACTIV Participa	ation Public		

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

Francis S. Collins, MD, PhD NIH Director From: Sharpless, Norman (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=340F3D07B6644DA7ACA53AB83DC066EF-SHARPLESSNE]

Sent: 5/15/2020 2:37:35 PM

To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Lowy, Douglas (NIH/NCI) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Santos, Michael (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

RE: standardized immunology assays to facilitate and speed approval of a vaccine against Covid 19 Subject:

Thx for sending

This is the sort of scientific effort that the NCI wishes to support with the Serology centers of excellence that we will be funding, and I will make sure they see our FOAs.

I think having an academic site doing testing for the clinical trials of ACTIV and then holding what I think would be CCI would be problematic, and these capacities for antibody detection and neutralization assays exist within the USG.

Ned

Original Message		,				
From: Collins, Francis (NIH/OD) [E]	b	6				
Sent: Thursday, May 14, 2020 9:27 PM						
To: Lowy, Douglas (NIH/NCI) [E]	b6		Michael (FNIH)		06	
Cc: Wholley, David (FNIH) [T]	h6	Sharpless,	Norman (NIH/NCI	:) [Ėj		i
b6 '		i				
Subject: FW: standardized immunology	assays to	facilitate and	speed approval	of a vaccine	against	Covid
10						

In case this is of interest.

Original Mess <u>age</u>		·-		
From: Ed Scolnick	b6			
Sent: Thursday, May 14, 2020	8:58 PM			
To: Marks, Peter (FDA/CBER)	b6	<u>: Daniel Wattendo</u>	orf	
. b6	Emilio Em	ini b6	; Fau	ci, Anthony
(NIH/NIAID) [E]   b6	; Collins	, Francis (NIH/OU) [E]	b6	; Tal Zaks
b6 '				•
Cc: Tander b6		g b6	; Ramnik Xav	ier
b6	; Schreiber Stu	art   b6	; Ramnik Xav ; David R	.Liu
b6 Ben	Cravatt {	o6 j; Michael Ro	osbash <b>b6</b>	;
'THOMAS''Cant'T'' b6	! Michael Z	Lin i b6	!	<u>.</u>
Subject: standardized immuno	logy assays to faci	litate and speed approv	/āTˈof a vaccine agaiı	nst Covid 19

Hi to All: For the past few days, I have been working with Dr Deb Hung a Member of the Broad Institute. Deb has been a member for 15 years and is a pioneer in Infectious disease. As the memo indicates, she had developed 2 assays which will be invaluable for the current Corona Virus Vaccine effort and is almost finished developing a 3rd one as noted in this memo.

Having these assays can potentially if trials go as planned lead to an approval of vaccines by the Fall. This would be analogous to Rapid approval of Cancer therapies. Additional studies would go on but early use of the Vaccine to stem the pandemic would be possible and would be a spectacular achievement for the Biomedical community.

The Broad is capable of running all the assays , sharing that data with the FDA which is supportive of the effort and keeping each company's data confidential from other companies. The Broad has proved that it can do hight throughput assays in its genotyping, sequencing and PCR based work and can now extend this capability to the immune assays needed to help the National vaccine effort

We urge you to approve this effort rapidly. In the HIV effort when I was at Merck we organized a Company consortium of 12 companies to share phase 2 data without showing structures of antiviral compounds. That allowed 2 companies to begin combination therapy

5 years earlier than normal and led to the triple therapy regimens that changed the face of HIV from a death notice to a manageable disease. This proposal can do the same for this pandemic.

I have included Katharine Jansen on the "to" list but am sending it to her private email address.

I implore you to help activate this effort as fast as possible free from the usual bureaucratic barriers. The effort can help the companies and most importantly help human beings who are terrified of becoming infected and prevent a second wave of infections in the fall, an event which would decimate the public and the country. b6

You can reach me by email or by cell phone Hung to answer your questions

I will make myself available and so will Deb

Best wishes Edward Scolnick From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]

**Sent**: 5/15/2020 2:38:50 PM

To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]

CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Yes, I did hear from Rao, Lutz and Grobler. Below are folks who have not responded:

# Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

# Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration

# Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader RTI International

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#### Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology Director and Chief Academic Officer Tulane University National Primate Research Center

# Frank Stegmeier, Ph.D.

Chief Scientific Officer KSQ Therapeutics

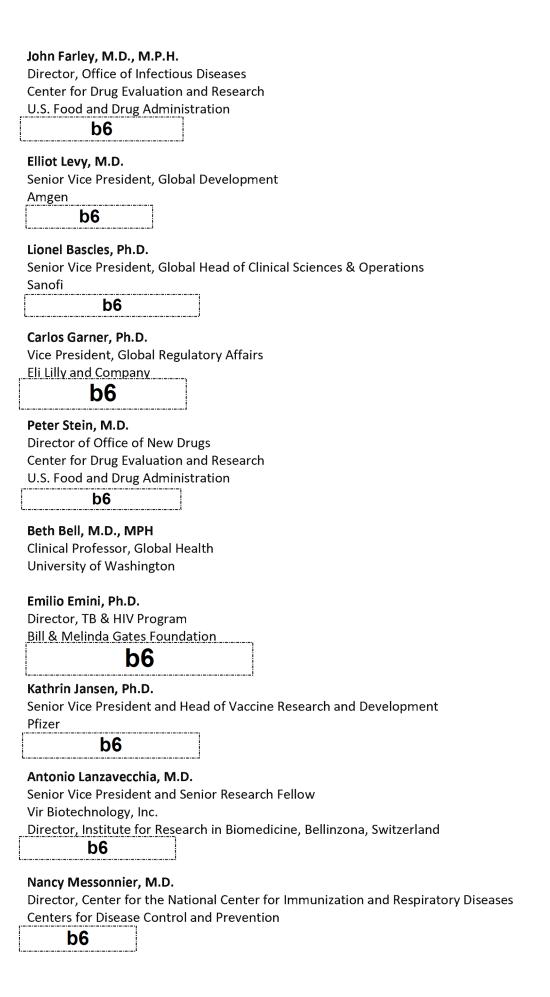
# Sylva Collins, Ph.D.

Director, Office of Biostatistics U.S. Food and Drug Administration

# Judith Currier, M.D.

Professor of Medicine University of California Los Angeles Division of Infectious Diseases Chair, AIDS Clinical Trial Group (ACTG)

b6



# Jonathan Seals, Ph.D.

Director, Strategic Science and Technology Biomedical Advanced Research and Development Authority

From: Parker, Ashley (NIH/OD) [E] <b>b6</b>
<b>Sent:</b> Friday, May 15, 2020 10:35 AM
To: Myles, Renate (NIH/OD) [E]
Cc: Brodd, Lauren (NIH/OD) [E] <b>b6</b>
Subject: RE: Time sensitive: Making your ACTIV Participation Public
Have you hear back from others? How many people are missing now?
Sylva, Beth and Jonathan – how will we handle getting their permissions?
From: Myles, Renate (NIH/OD) [E] <b>b6</b>
<b>Sent:</b> Friday, May 15, 2020 10:33 AM
To: Parker, Ashley (NIH/OD) [E]
Cc: Brodd, Lauren (NIH/OD) [E] 66
Subject: RE: Time sensitive: Making your ACTIV Participation Public
Thanks, Ashley and Lauren. Very helpful.
From: Parker, Ashley (NIH/OD) [E] <b>b6</b>
<b>Sent:</b> Friday, May 15, 2020 10:27 AM
To: Mules, Benete (NIH/OD) [E]
Cc: Brodd, Lauren (NIH/OD) [E] <b>b6</b>
Subject: RE: Time sensitive: Making your ACTIV Participation Public
Hi Renate,
Sparing FC's inbox and others.
With many thanks to Lauren for helping us with this. Please see edits attached and below – the alphabetizing of the
names can be ignored as this is updated in the revised version you've provided.
A few minor edits:
Co-chairs of the working groups should be identified
Consistency with MD or M.D.
Minor change to John Mellors
Thanks,
Ashley
From: Myles, Renate (NIH/OD) [E] <b>b6</b>
Sent: Friday, May 15, 2020 9:21 AM
To: Parker, Ashley (NIH/OD) [E] b6 Collins, Francis (NIH/OD) [E] b6
Cc: Allen-Gifford, Patrice (NIH/OD) [E] b6 Wooldridge, Shannon (NIH/OD) [E]

b6

Pollock, Rachel (NIH/OD) [E]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Ashley:

b6

communications. Please let me know of any changes.
Thanks, Renate
From: Parker, Ashley (NIH/OD) [E] b6  Sent: Friday, May 15, 2020 9:11 AM  To: Myles, Renate (NIH/OD) [E] b6 Collins, Francis (NIH/OD) [E] b6  Cc: Allen-Gifford, Patrice (NIH/OD) [E] b6 Wooldridge, Shannon (NIH/OD) [E] b6 ; Pollock, Rachel (NIH/OD) [E] b6
Subject: RE: Time sensitive: Making your ACTIV Participation Public
Hi Renate,
I've added the emails below but we have a major version control issues. I've been working with Cheryl to receive updates and did not have Sylvia Collins, Beth Bell and Jonathan Seals and apparently they are listed on a separate list the FNIH communications team is tracking.
We can send follow up emails to everyone except for those three – they will need to be contacted.
Moving forward, it may be best for you to receive updates from the communications team — FNIH is managing multiple spreadsheets one for the emails Cheryl is managing to schedule meetings and a separate list for the communications office.
Ralph Baric, Ph.D. William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health
<b>b6</b>
Damon Deming, Ph.D. Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration  b6
Greg Gatto, Ph.D.  Drug Development Regulatory Project Leader  RTI International  b6
Jay Grobler, Ph.D. Director, Infectious Disease Biology Merck & Co., Inc.  b6
Cat Lutz, Ph.D. Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center
The Jackson Laboratory
<b>b6</b>

Attached is the full list of members currently listed on the website in staging. I received the list from FNIH

David Payne, Ph.D.
Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline
b6
Louise Pitt, Ph.D.
Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases
b6
<u>i</u>
Srinivas Rao, DVM, Ph.D.
Global Head, Translational In Vivo Models Global Research Platform
Sanofi
b6
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Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center <b>b6</b>
<u>[</u> ]
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Chief Scientific Officer
KSQ Therapeutics
b6
<u> </u>
Sylva Collins, Ph.D.
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Judith Currier, M.D.
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Chair, AIDS Clinical Trial Group (ACTG)
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Eli Lilly and Company	
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To: Collins, Francis (NIH/OD) [E] b6	
Cc: Allen-Gifford, Patrice (NIH/OD) [E] b6 Parker, Ashley (NIH/OD)	
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[E] <b>b6</b>	
Subject: FW: Time sensitive: Making your ACTIV Participation Public	

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<b>Sent:</b> Thursday, May 14, 2020 11:00 AM
To: Collins Francis (NIH/OD) [F]
Cc: Myles, Renate (NIH/OD) [E] Meltzer, Abbey (FNIH) [T] b6 Wholley, David
(FNIH) [T] <b>b6</b>
Subject: Time sensitive: Making your ACTIV Participation Public
Dear ACTIV Colleagues:
Yes, this message is for you, though your address was in the bcc line!
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available information, but we would like add the ACTIV leadership and working group members. Your representation on
ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow,
Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.
Tinday, May 15, it you agree to be listed oil the web site as part of the ACTIV team.

Thanks, Francis

Francis S. Collins, MD, PhD NIH Director

Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP] Sent: 5/15/2020 2:57:39 PM To: Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; ; Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; b6 Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-gashufm] CC: Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy b6 ; Jansen, Kathrin Hughes, Eric b6 Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group b6 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes ; Diamond, Michael Dana Carluccio Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];

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	Simon, Dina (NIH/OD) [C] [/	o=ExchangeLabs/ou=Exch	ange Administrative Gr	oup
	(FYDIBOHF23SPDLT)/cn=Re	cipients/cn=e02345fa5d1	d4d7eaf4e0f3da58bc1a	c-simondm]; Burrus-Shaw, Cyndi
	(NIH/OD) [E] [/o=Exchangel			
	(FYDIBOHF23SPDLT)/cn=Re	cipients/cn=5bbac95b1f6		f6-shawcy]; Rodriguez, Robin D
		ve Frankowski	b6	; Lowy, Douglas (NIH/NCI) [E]
	[/o=ExchangeLabs/ou=Exch	-	•	Coloured Clarence Clint (AULIAID)
	[E] [/o=ExchangeLabs/ou=E			Ba-lowyd]; Florence, Clint (NIH/NIAID)
	(FYDIBOHF23SPDLT)/cn=Re			fe-florencewel: <b>h6</b>
	b6			[/o=ExchangeLabs/ou=Exchange
	i	i		lbe3bf063f925ac15f02-hildsa]
Subject:	RE: ACTIV Preclinical working			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Attachments:	Therapeutic information re			
Dear Preclinio	cal working group and invi	tees,		
Part of our tir	me today will be discussing	g the therapeutic inform	nation request form. I	will be projecting this for discussion,
	-		•	has additions from the clinical
•	p (thank you clinical worki			
	, , , , , , , , , , , , , , , , , , , ,			
Looking forwa	ard to our discussion.			
Ü				
Joe				
Original A	ppointment			
	ski, Joseph (FNIH) [T]			
	y, April 14, 2020 6:48 PM			
То		Cihlar; b6	Menetski, Jo	seph (FNIH) [T];
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		D6		
	b6		Parker, As	hley (NIH/OD) [E]; Collins, Francis
(NIH/OD) [E];		Adams, Peter	(OS/ASPR/BARDA); R	ao, Srinivas /US; Anderson, James
(NIH/OD) [E];	Qashu, Felicia (NIH/OD) [	<u> </u>		
Cc: Nancy Hai	igwood; Wholley, David (F	NIH) [T]; Austin, Christo	pher (NIH/NCATS) [E]	; Melencio, Cheryl (FNIH) [T]; Colvis,
Christine (NIF	I/NCATS) [E]; Desrosiers, E	Betsy; Hughes, Eric; Jans	en, Kathrin; Kurilla, M	lichael (NIH/NCATS) [E]; Lowy,
Douglas (NCI)	; Read, Sarah (NIH/NIAID)	[E]; Tountas, Karen (FN	IH) [T]; Santos, Micha	el (FNIH) [T]; Adam, Stacey (FNIH)
[T]; James, St	ephanie (FNIH) [T]; Alvare	z, Rosa Maria; Kim, Eliza	beth; Tolman, Brett;	Wachtel, Jonathan; Prabhavathi
Fernandes; D	iamond, Michael; Rose Li;	Dana Carluccio; Lagos, I	Enrique (NIH/NCATS)	[E]; Jonson, Samantha (NIH/NCATS)
[E]; Gonzalez,	, Nina; Simon, Dina (NIH/C	D) [C]; Burrus-Shaw, Cy	ndi (NIH/OD) [E]; Rod	riguez, Robin D; Dave Frankowski;
Lowy, Dougla	s (NIH/NCI) [E]; Florence,	Clint (NIH/NIAID) [E];	b6	; Hild, Sheri (NIH/OD)
[E]				
Subject: ACTI	V Preclinical working grou	p (Friday meeting)		
When: Friday	, May 15, 2020 11:00 AM-	12:00 PM (UTC-05:00) F	astern Time (US & Ca	ınada).
Where:		b6		
Holding time				
Joseph Mene	tski is inviting you to a sch	eduled Zoom meeting.		
Join Zoom Me	eeting			
		b6		
			:	

Meeting ID: <b>b</b> 6		
Password: <b>b6</b>		
One tap mobile		
b	6	US (New York) US (Chicago)
Dial by your location		
	US (New York)	
	US (Chicago)	
L C	US	
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į	US (San Jose)	
<u></u>	US (San Jose)	
Meeting ID: b6		
Password: <b>b6</b>		
Find your local numb	er:	b6

**Sent**: 5/15/2020 3:21:04 PM

To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]

CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

I'm on a call with Cheryl now and working group members are being added in real time – additions that come in today and over the weekend etc. will have to added on the next wave?

FNIH is forwarding Francis' email to Beth, Sylva, and Jonathan – they were not on her list.

From: Myles, Renate (NIH/OD) [E] **b6** 

Sent: Friday, May 15, 2020 11:11 AM

To: Parker, Ashley (NIH/OD) [E]
Cc: Brodd, Lauren (NIH/OD) [E]

b6

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Just heard from Judith Currier. Removed her from the list below. 19 more to go.

From: Myles, Renate (NIH/OD) [E]

Sent: Friday, May 15, 2020 10:39 AM

To: Parker, Ashley (NIH/OD) [E] Cc: Brodd, Lauren (NIH/OD) [E]

**b6** 

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Yes, I did hear from Rao, Lutz and Grobler. Below are folks who have not responded:

# Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

# Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration

# Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader RTI International

# David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit GlaxoSmithKline

# Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences United States Army Medical Research Institute of Infectious Diseases

Jay Rappaport, Ph.D.	
Professor of Microbiology and Immunology	
Director and Chief Academic Officer	
Tulane University National Primate Research Center	
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Frank Stagmajor, Bh D	
Frank Stegmeier, Ph.D.	
Chief Scientific Officer	
KSQ Therapeutics	
Sylva Collins, Ph.D.	
Director, Office of Biostatistics	
U.S. Food and Drug Administration	
0.5. 1 ood and Drug Administration	
John Forder, AAD, AAD II	
John Farley, M.D., M.P.H.	
Director, Office of Infectious Diseases	
Center for Drug Evaluation and Research	
U.S. Food and Drug Administration	
<b>b6</b>	
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Elliot Love M.D.	
Elliot Levy, M.D.	
Senior Vice President, Global Development	
Amgen	
b6	
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Lionel Bascles, Ph.D.	
Senior Vice President, Global Head of Clinical Sciences & Operations	
Sanofi	
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Carlos Garner, Ph.D.	
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Carlos Garner, Ph.D.	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company b6	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6  Peter Stein, M.D.	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6  Peter Stein, M.D. Director of Office of New Drugs	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6  Peter Stein, M.D. Director of Office of New Drugs Center for Drug Evaluation and Research	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6  Peter Stein, M.D. Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6  Peter Stein, M.D. Director of Office of New Drugs Center for Drug Evaluation and Research	
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Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6  Peter Stein, M.D. Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration  b6	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6  Peter Stein, M.D. Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration  b6  Beth Bell, M.D., MPH Clinical Professor, Global Health	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6  Peter Stein, M.D. Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration  b6  Beth Bell, M.D., MPH	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6  Peter Stein, M.D. Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration  b6  Beth Bell, M.D., MPH Clinical Professor, Global Health University of Washington	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6  Peter Stein, M.D. Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration  b6  Beth Bell, M.D., MPH Clinical Professor, Global Health University of Washington  Emilio Emini, Ph.D.	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6  Peter Stein, M.D. Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration  b6  Beth Bell, M.D., MPH Clinical Professor, Global Health University of Washington  Emilio Emini, Ph.D. Director, TB & HIV Program	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6  Peter Stein, M.D. Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration  b6  Beth Bell, M.D., MPH Clinical Professor, Global Health University of Washington  Emilio Emini, Ph.D.	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6  Peter Stein, M.D. Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration  b6  Beth Bell, M.D., MPH Clinical Professor, Global Health University of Washington  Emilio Emini, Ph.D. Director, TB & HIV Program Bill & Melinda Gates Foundation	
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Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6  Peter Stein, M.D. Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration  b6  Beth Bell, M.D., MPH Clinical Professor, Global Health University of Washington  Emilio Emini, Ph.D. Director, TB & HIV Program Bill & Melinda Gates Foundation  b6  Kathrin Jansen, Ph.D.	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company	
Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6  Peter Stein, M.D. Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration  b6  Beth Bell, M.D., MPH Clinical Professor, Global Health University of Washington  Emilio Emini, Ph.D. Director, TB & HIV Program Bill & Melinda Gates Foundation  b6  Kathrin Jansen, Ph.D.	

# Antonio Lanzavecchia, M.D. Senior Vice President and Senior Research Fellow Vir Biotechnology, Inc. Director, Institute for Research in Biomedicine, Bellinzona, Switzerland b₆ Nancy Messonnier, M.D. Director, Center for the National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention b6 Jonathan Seals, Ph.D. Director, Strategic Science and Technology Biomedical Advanced Research and Development Authority From: Parker, Ashley (NIH/OD) [E] Sent: Friday, May 15, 2020 10:35 AM To: Myles, Renate (NIH/OD) [E] **b6** Cc: Brodd, Lauren (NIH/OD) [E] Subject: RE: Time sensitive: Making your ACTIV Participation Public Have you hear back from others? How many people are missing now? Sylva, Beth and Jonathan – how will we handle getting their permissions? From: Myles, Renate (NIH/OD) [E] Sent: Friday, May 15, 2020 10:33 AM To: Parker, Ashley (NIH/OD) [E] **b6** Cc: Brodd, Lauren (NIH/OD) [E] Subject: RE: Time sensitive: Making your ACTIV Participation Public Thanks, Ashley and Lauren. Very helpful. From: Parker, Ashley (NIH/OD) [E] b6 Sent: Friday, May 15, 2020 10:27 AM To: Myles, Renate (NIH/OD) [E] **b6** Cc: Brodd, Lauren (NIH/OD) [E] Subject: RE: Time sensitive: Making your ACTIV Participation Public Hi Renate, Sparing FC's inbox and others.

With many thanks to Lauren for helping us with this. Please see edits attached and below - the alphabetizing of the

A few minor edits:

· Co-chairs of the working groups should be identified

names can be ignored as this is updated in the revised version you've provided.

- Consistency with MD or M.D.
- Minor change to John Mellors

Thanks,
Ashley  France Addition Brown to (NULL/OR) [F]   bG
From: Myles, Renate (NIH/OD) [E] <b>b6</b> Sent: Friday, May 15, 2020 9:21 AM
To: Parker, Ashley (NIH/OD) [E] b6 Collins, Francis (NIH/OD) [E] b6
Cc: Allen-Gifford, Patrice (NIH/OD) [E] b6 Wooldridge, Shannon (NIH/OD) [E]
<b>b6</b> ; Pollock, Rachel (NIH/OD) [E] <b>b6</b>
Subject: RE: Time sensitive: Making your ACTIV Participation Public
Hi Ashley:
Attached is the full list of members currently listed on the website in staging. I received the list from FNIH communications. Please let me know of any changes.
Thanks, Renate
From: Parker, Ashley (NIH/OD) [E] b6
Sent: Friday, May 15, 2020 9:11 AM
To: Myles, Renate (NIH/OD) [E] b6   Collins, Francis (NIH/OD) [E] b6
Cc: Allen-Gifford, Patrice (NIH/OD) [E] b6 Wooldridge, Shannon (NIH/OD) [E] b6 b6
Subject: RE: Time sensitive: Making your ACTIV Participation Public
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Hi Renate,
I've added the emails below but we have a major version control issues. I've been working with Cheryl to receive updates and did not have Sylvia Collins, Beth Bell and Jonathan Seals and apparently they are listed on a separate list the FNIH communications team is tracking.
We can send follow up emails to everyone except for those three – they will need to be contacted.
Moving forward, it may be best for you to receive updates from the communications team — FNIH is managing multiple spreadsheets one for the emails Cheryl is managing to schedule meetings and a separate list for the communications office.
Ralph Baric, Ph.D.
William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health
<b>b6</b>
Damon Deming, Ph.D.
Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration
b6
Green Cotton Bh D
Greg Gatto, Ph.D.  Drug Development Regulatory Project Leader
Drug Development Regulatory Project Leader RTI International
b6

Jay Grobler, Ph.D.
Director, Infectious Disease Biology
Merck & Co., Inc.
b6
Cat Lutz, Ph.D.
Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center
The Jackson Laboratory
b6
David Payne, Ph.D.
Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline
b6
<u> </u>
b6
Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases
b6
Srinivas Rao, DVM, Ph.D.
Global Head, Translational In Vivo Models Global Research Platform
Sanofi
<b>b6</b>
Jay Rappaport, Ph.D.
Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center
b6
Frank Stegmeier, Ph.D.
Chief Scientific Officer
KSQ Therapeutics
b6
Sylva Collins, Ph.D.
Director, Office of Biostatistics
U.S. Food and Drug Administration
b6
<u>i</u> !
Judith Currier, M.D.
Professor of Medicine
University of California Los Angeles
Division of Infectious Diseases
Chair, AIDS Clinical Trial Group (ACTG)
b6
John Farley, M.D., M.P.H.
Director, Office of Infectious Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
h6

Elliot Levy, M.D.
Senior Vice President, Global Development
Amgen
b6
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Lionel Bascles, Ph.D.
Senior Vice President, Global Head of Clinical Sciences & Operations
Sanofi
b6
Carlos Garner, Ph.D.
Vice President, Global Regulatory Affairs
Eli Lilly and Company
<b>b6</b>
Peter Stein, M.D.
Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
b6
Beth Bell, M.D., MPH
Clinical Professor, Global Health
University of Washington
b6
Emilio Emini. Ph.D.
Emilio Emini, Ph.D.  Director, TB & HIV Program
Director, TB & HIV Program
Director, TB & HIV Program  Bill & Melinda Gates Foundation
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Director, TB & HIV Program Bill & Melinda Gates Foundation  b6
Director, TB & HIV Program  Bill & Melinda Gates Foundation  b6  Kathrin Jansen, Ph.D.
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From: Myles, Renate (	NIH/OD) [E]	b6		
Sent: Friday, May 15, 2	020 7:53 AM			
<b>To:</b> Collins, Francis (NIII <b>Cc:</b> Allen-Gifford, Patric	H/OD) [E] [	b6		
Cc: Allen-Gifford, Patrio	ce (NIH/OD) [E]	b6	Parker, Ashley (I	NIH/OD) [E]
b6	; Wooldridge, S	hannon (NIH/OD) [E]	b6	; Pollock, Rachel (NIH/OD)
[E] <b>b6</b>		1		
Subject: FW: Time sens	sitive: Making your	ACTIV Participation P	ublic	
Hi Francis:				
Below is the list of 23 v	people who have	not yet responded to	our email. I cross refere	nced these names with the email
list that Ashely sent an	d pulled addresses	from that list. I didn't	find emails for a numbe	r of these people, but I know
there was a second rou	ind that went out	using emails I don't ha	ve. Hoping Ashley can pr	ovide the missing emails.
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## Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

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## Frank Stegmeier, Ph.D.

Chief Scientific Officer KSQ Therapeutics

## Sylva Collins, Ph.D.

Director, Office of Biostatistics U.S. Food and Drug Administration

## Judith Currier, M.D.

Professor of Medicine University of California Los Angeles Division of Infectious Diseases Chair, AIDS Clinical Trial Group (ACTG)

b6

## John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases Center for Drug Evaluation and Research U.S. Food and Drug Administration

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Pfizer	nd Development		
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Senior Vice President and Senior Research Fellow			
Vir Biotechnology, Inc.			
Director, Institute for Research in Biomedicine, Bellinz	ona, Switzerland		
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Nancy Messonnier, M.D.			
Director, Center for the National Center for Immunization	tion and Respiratory Diseases		
Centers for Disease Control and Prevention	tion and Respiratory Diseases		
b6			
Jonathan Seals, Ph.D.			
Director, Strategic Science and Technology			
Biomedical Advanced Research and Development Autl	hority		
	<u>-</u>		
From: Collins, Francis (NIH/OD) [E] b6			
Sent: Thursday, May 14, 2020 11:00 AM			
To: Collins, Francis (NIH/OD) [E]	NA-14 Al-1 (FNIII) (T1	L 0	
cc. wyles, heriate (will) OD/ [L]	Meltzer, Abbey (FNIH) [T]	b6	Wholley, David
(FNIH) [T] <b>b6 Subject:</b> Time sensitive: Waking your ACTIV Participati	on Public		
Subject. Time sensitive, Making your Activ Farticipati	on rubile		
Dear ACTIV Colleagues:			
2			
Yes, this message is for you, though your address was	in the bcc line!		
NIH would like to launch an ACTIV webpage to provide	e stakeholders with a central reso	urce for infor	mation about our
efforts, including announcements, scientific papers, ar			
available information, but we would like add the ACTI			
ACTIV demonstrates the breadth and depth of experti			
send your responses to me, cc'ing Renate Myles, Abb	•	oy 12:00 p.m.	ET tomorrow,
Friday, May 15, if you agree to be listed on the web s	ite as part of the ACTIV team.		
Thanks			
Thanks,			
Francis			

Francis S. Collins, MD, PhD

NIH Director

APAR0000028899

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]

**Sent**: 5/15/2020 3:25:42 PM

To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]

CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Yes, definitely.

From: Parker, Ashley (NIH/OD) [E] 66

Sent: Friday, May 15, 2020 11:22 AM

To: Myles, Renate (NIH/OD) [E]

Cc: Brodd, Lauren (NIH/OD) [E] **b6** 

Subject: RE: Time sensitive: Making your ACTIV Participation Public

I'm on a call with Cheryl now and working group members are being added in real time – additions that come in today and over the weekend etc. will have to added on the next wave?

FNIH is forwarding Francis' email to Beth, Sylva, and Jonathan - they were not on her list.

From: Myles, Renate (NIH/OD) [E] b6
Sent: Friday, May 15, 2020 11:11 AM

To: Parker, Ashley (NIH/OD) [E] Cc: Brodd, Lauren (NIH/OD) [E]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Just heard from Judith Currier. Removed her from the list below. 19 more to go.

From: Myles, Renate (NIH/OD) [E] Sent: Friday, May 15, 2020 10:39 AM

To: Parker, Ashley (NIH/OD) [E] Cc: Brodd, Lauren (NIH/OD) [E]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Yes, I did hear from Rao, Lutz and Grobler. Below are folks who have not responded:

#### Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

#### Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration

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**b6** 

## Beth Bell, M.D., MPH

Clinical Professor, Global Health University of Washington

Emilio Emini, Ph.D. Director, TB & HIV Program Bill & Melinda Gates Foundation  b6
Kathrin Jansen, Ph.D. Senior Vice President and Head of Vaccine Research and Development Pfizer
<b>b6</b>
Antonio Lanzavecchia, M.D. Senior Vice President and Senior Research Fellow Vir Biotechnology, Inc. Director, Institute for Research in Biomedicine, Bellinzona, Switzerland  66
Nancy Messonnier, M.D.  Director, Center for the National Center for Immunization and Respiratory Diseases  Centers for Disease Control and Prevention  6
Jonathan Seals, Ph.D. Director, Strategic Science and Technology Biomedical Advanced Research and Development Authority
From: Parker, Ashley (NIH/OD) [E] b6  Sent: Friday, May 15, 2020 10:35 AM  To: Myles, Renate (NIH/OD) [E] b6  Cc: Brodd, Lauren (NIH/OD) [E] b6  Subject: RE: Time sensitive: Making your ACTIV Participation Public  Have you hear back from others? How many people are missing now?  Sylva, Beth and Jonathan – how will we handle getting their permissions?
Sylva, Beth and Jonathan – now will we handle getting their permissions:
From: Myles, Renate (NIH/OD) [E] b6  Sent: Friday, May 15, 2020 10:33 AM  To: Parker, Ashley (NIH/OD) [E] b6  Cc: Brodd, Lauren (NIH/OD) [E] b6  Subject: RE: Time sensitive: Making your ACTIV Participation Public
Thanks, Ashley and Lauren. Very helpful.
From: Parker, Ashley (NIH/OD) [E] b6  Sent: Friday, May 15, 2020 10:27 AM  To: Myles, Renate (NIH/OD) [E] b6  Cc: Brodd, Lauren (NIH/OD) [E] b6  Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Renate,

Sparing FC's inbox and others.

With many thanks to Lauren for helping us with this. Please see edits attached and below – the alphabetizing of the names can be ignored as this is updated in the revised version you've provided.

#### A few minor edits:

- · Co-chairs of the working groups should be identified
- Consistency with MD or M.D.
- Minor change to John Mellors

Thanks, Ashley				
From: Myles, Renate (NIH/OD) [E]	b6			
Sent: Friday, May 15, 2020 9:21 AM  To: Parker, Ashley (NIH/OD) [E]  Cc: Allen-Gifford, Patrice (NIH/OD) [E]  b6  ; Pollock, F	h6	Calling Francis (NULL/OD) [E]	h6 !	
Co. Allen Gifford Patrice (NIH/OD) [E]	DO LC	Collins, Francis (NIH/OD) [E]	DO (NIH/OD) [E]	
b6 : Pollock B	od Pachel (NIH/OD	vvooldridge, shariii	ion (Nin/OD) [E]	
Subject: RE: Time sensitive: Making your AG	CTIV Participati	op Public		
Subject. NE. Time sensitive. Making your A	criv Farticipati	on rubiic		
Hi Ashley:				
The Ashrey.				
Attached is the full list of members current communications. Please let me know of an		website in staging. I received the	e list from FNIH	
Thanks, Renate				
From: Parker, Ashley (NIH/OD) [E] { Sent: Friday, May 15, 2020 9:11 AM	b6			
To: Myles Penate (NIH/OD) [F1]	h6 'C	olling Francis (NIH/OD) [F]	h6	
To: Myles, Renate (NIH/OD) [E]  Cc: Allen-Gifford, Patrice (NIH/OD) [E]  b6 Pollock, F	be je	Wooldridge Shann	on (NIH/OD) [F]	
b6 Pollock R	od Pachel (NIIH/OD	TEY LO	ion (Min/OD) [L]	
Subject: RE: Time sensitive: Making your AG	CTIV Participati	on Public		
Dawjett RE. Time Sensitive. Making your A	cit i ai deipad	on i done		
Hi Renate,				

I've added the emails below but we have a major version control issues. I've been working with Cheryl to receive updates and did not have Sylvia Collins, Beth Bell and Jonathan Seals and apparently they are listed on a separate list the FNIH communications team is tracking.

We can send follow up emails to everyone except for those three – they will need to be contacted.

Moving forward, it may be best for you to receive updates from the communications team – FNIH is managing multiple spreadsheets one for the emails Cheryl is managing to schedule meetings and a separate list for the communications office.

## Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

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Virologist, Division of Antiviral Products, Office of New Drugs
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Greg Gatto, Ph.D.
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United States Army Medical Research Institute of Infectious Diseases
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Professor of Medicine

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Director, Center for the National Center for Immunization and Respiratory Diseases  Centers for Disease Control and Prevention  b6
Jonathan Seals, Ph.D.
Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority
b6
From: Myles, Renate (NIH/OD) [E] <b>b6</b> Sent: Friday, May 15, 2020 7:53 AM
To: Collins, Francis (NIH/OD) [E] 66
Cc: Allen-Gifford, Patrice (NIH/OD) [E] b6 ; Parker, Ashley (NIH/OD) [E]
Cc: Allen-Gifford, Patrice (NIH/OD) [E] b6 ; Parker, Ashley (NIH/OD) [E] b6 ; Wooldridge, Shannon (NIH/OD) [E] b6 ; Pollock, Rachel (NIH/OD)
[E] b6
Subject: FW: Time sensitive: Making your ACTIV Participation Public
Hi Francis:
Below is the list of 23 vpeople who have not yet responded to your email. I cross referenced these names with the email list that Ashely sent and pulled addresses from that list. I didn't find emails for a number of these people, but I know there was a second round that went out using emails I don't have. Hoping Ashley can provide the missing emails.
<b>b6</b>

## Ralph Baric, Ph.D.

Nancy Messonnier, M.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

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## Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader RTI International

## Jay Grobler, Ph.D.

Director, Infectious Disease Biology Merck & Co., Inc.

## Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center The Jackson Laboratory

#### David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit GlaxoSmithKline

#### Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

## Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform Sanofi

## Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology Director and Chief Academic Officer Tulane University National Primate Research Center

#### Frank Stegmeier, Ph.D.

Chief Scientific Officer KSQ Therapeutics

## Sylva Collins, Ph.D.

Director, Office of Biostatistics U.S. Food and Drug Administration

#### Judith Currier, M.D.

Professor of Medicine University of California Los Angeles Division of Infectious Diseases Chair, AIDS Clinical Trial Group (ACTG)

b6

#### John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases Center for Drug Evaluation and Research U.S. Food and Drug Administration

b6

## Elliot Levy, M.D.

Senior Vice President, Global Development

Amgen

b6

#### Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi

he

# Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs

Eli Lilly and Company

b6

Peter Stein, M.D.
Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
b6
Beth Bell, M.D., MPH
Clinical Professor, Global Health
University of Washington
Emilio Emini, Ph.D.
Director, TB & HIV Program
Bill & Melinda Gates Foundation
b6
Kathrin Jansen, Ph.D.
Senior Vice President and Head of Vaccine Research and Development
Pfizer
b6
Antonio Lanzavecchia, M.D.  Senior Vice President and Senior Research Fellow  Vir Biotechnology, Inc.  Director, Institute for Research in Biomedicine, Bellinzona, Switzerland  b6  Nancy Messonnier, M.D.  Director, Center for the National Center for Immunization and Respiratory Diseases  Centers for Disease Control and Prevention  b6  Jonathan Seals, Ph.D.  Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority
From: Collins, Francis (NIH/OD) [E] b6
Sent: Thursday, May 14, 2020 11:00 AM
To: Collins, Francis (NIH/OD) [E]  Co: Myles Renate (NIH/OD) [F]  Meltzer Abbey (FNIH) [T]  h6 Wholley David
wholey, have (init) = 1
(FNIH) [1] <b>b6</b> Subject: Time sensitive: Making your ACTIV Participation Public
Dear ACTIV Colleagues:
Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow,

Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

Francis S. Collins, MD, PhD NIH Director

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/15/2020 4:54:29 PM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner ] Eric Hughes Keith Gottesdiener b6 ; Amanda Peppercorn Proschan, Michael b6 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael ]; Wung, Peter /US b6 Pamela Tenaerts, M.D. ; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy ; Beumont-Mauviel, Maria [JRDUS] **b6** ; Peeters, Monika [JRDBE] b6 Woodfall, Brian [JRDUS] Van Heeswijk, Rolf [JRDBE] b6 CC: b6 ; Macone, Erin Mary Biggs Demarcus Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina i]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc] Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #17 Attachments: ACTIV Therapeutics-Clinical MP Subgroup 15May2020 Meeting Guide.pdf Location: b6 Start: 5/15/2020 5:00:00 PM 5/15/2020 6:00:00 PM End: Show Time As: Tentative

Required Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo Attendees: (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amand

(FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne

(FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters,

Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]

Optional Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley

Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Stacey Adam is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting	
	b6
Meeting ID: <b>b6</b>	
Password: b6	
One tap mobile	
b6	US (Chicago) US (New York)
Dial by your location	
US (Chicago) US (New York) US (Germantown) US (Houston) US (San Jose) US (San Jose) US (Tacoma)	
Meeting ID: <b>b6</b>	
Password: b6	
Find your local number:	b6

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]

Sent: 5/15/2020 5:18:14 PM

To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]

CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

We will need to ask Rachel. If you did not see it go out, I would assume not since you were on the cc line, right?

From: Myles, Renate (NIH/OD) [E]

Sent: Friday, May 15, 2020 1:14 PM

To: Parker, Ashley (NIH/OD) [E][ b6 Cc: Brodd, Lauren (NIH/OD) [E]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Did ExecSec send another message this morning?

From: Parker, Ashley (NIH/OD) [E] b6 **Sent:** Friday, May 15, 2020 1:10 PM

To: Myles, Renate (NIH/OD) [E] **b6** Cc: Brodd, Lauren (NIH/OD) [E]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Cheryl sent a message to Beth, Sylva, and Jonathan giving them until 2pm today.

I think we can reply to FC emails he sent yesterday, adding those non responders to the bcc line letting them know we are following up if they can let us know by 3pm today or ASAP unless you think this should come from FC directly.

We would need to remove the 3 names listed above.

From: Myles, Renate (NIH/OD) [E] b6

**Sent:** Friday, May 15, 2020 1:01 PM

To: Parker, Ashley (NIH/OD) [E] **b6** Cc: Brodd, Lauren (NIH/OD) [E] -

Subject: RE: Time sensitive: Making your ACTIV Participation Public

We can push the website live whenever we're ready, but we would have to remove the list of folks below. How should we proceed? Should I ask Francis?

From: Parker, Ashley (NIH/OD) [E] b6

Sent: Friday, May 15, 2020 11:22 AM

**To:** Myles, Renate (NIH/OD) [E]

b6 Cc: Brodd, Lauren (NIH/OD) [E]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

I'm on a call with Cheryl now and working group members are being added in real time – additions that come in today and over the weekend etc. will have to added on the next wave?

FNIH is forwarding Francis' email to Beth, Sylva, and Jonathan – they were not on her list.

From: Myles, Renate (NIH/OD) [E] **b6** 

Sent: Friday, May 15, 2020 11:11 AM

To: Parker, Ashley (NIH/OD) [E] Cc: Brodd, Lauren (NIH/OD) [E]

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Just heard from Judith Currier. Removed her from the list below. 19 more to go.

From: Myles, Renate (NIH/OD) [E] Sent: Friday, May 15, 2020 10:39 AM

To: Parker, Ashley (NIH/OD) [E] Cc: Brodd, Lauren (NIH/OD) [E] **b6** 

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Yes, I did hear from Rao, Lutz and Grobler. Below are folks who have not responded:

## Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

#### Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration

#### Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader RTI International

#### David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit GlaxoSmithKline

#### Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences United States Army Medical Research Institute of Infectious Diseases

#### Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology Director and Chief Academic Officer Tulane University National Primate Research Center

## Frank Stegmeier, Ph.D.

Chief Scientific Officer KSQ Therapeutics

## Sylva Collins, Ph.D.

Director, Office of Biostatistics U.S. Food and Drug Administration

John Farley, M.D., M.P.H.  Director, Office of Infectious Diseases  Center for Drug Evaluation and Research  U.S. Food and Drug Administration
U.S. Food and Drug Administration <b>b6</b>
<u>[</u> ]
Elliot Levy, M.D. Senior Vice President, Global Development
Amgen
<b>b6</b>
Lionel Bascles, Ph.D.
Senior Vice President, Global Head of Clinical Sciences & Operations
Sanofi
b6
Carlos Garner, Ph.D.
Vice President, Global Regulatory Affairs
Eli Lilly and Company
<u>b6</u>
Peter Stein, M.D.
Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
b6
<u> </u>
Beth Bell, M.D., MPH
Clinical Professor, Global Health
University of Washington
Emilio Emini, Ph.D.
Director, TB & HIV Program
Bill & Melinda Gates Foundation
b6
Kathrin Jansen, Ph.D.
Senior Vice President and Head of Vaccine Research and Development
Pfizer
b6
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Antonio Lanzavecchia, M.D. Senior Vice President and Senior Research Fellow
Vir Biotechnology, Inc. <u>Director, Institute for Re</u> search in Biomedicine, Bellinzona, Switzerland
b6
Nancy Messonnier, M.D.
Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
b6

# Jonathan Seals, Ph.D.

Hi Ashley:

Director, Strategic Science and Technology Biomedical Advanced Research and Development Authority

From: Parker, Ashley (NIH/OD) [E] b6 Sent: Friday, May 15, 2020 10:35 AM
To: Myles, Renate (NIH/OD) [E]
Cc: Brodd, Lauren (NIH/OD) [E] <b>b6</b>
Subject: RE: Time sensitive: Making your ACTIV Participation Public
Subject. NE. Time sensitive. Making your Activit anticipation i ubile
Have you hear back from others? How many people are missing now?
Sylva, Beth and Jonathan – how will we handle getting their permissions?
From: Myles, Renate (NIH/OD) [E] <b>b6</b>
Sent: Friday, May 15, 2020 10:33 ANT
To: Parker, Ashley (NIH/OD) [E] 66
CC. Diodd, Eddich (Willy OD) [2]
Subject: RE: Time sensitive: Making your ACTIV Participation Public
Thanks, Ashley and Lauren. Very helpful.
From: Parker, Ashley (NIH/OD) [E] b6
<b>Sent:</b> Friday, May 15, 2020 10:27 AM
To: Myles Penete (NIH/OD) [5]
Cc: Brodd, Lauren (NIH/OD) [E] b6
Subject: RE: Time sensitive: Making your ACTIV Participation Public
Subject. RE. Time sensitive. Making your ACTIV Farticipation Fublic
Hi Renate,
Sparing FC's inbox and others.
With many thanks to Lauren for helping us with this. Please see edits attached and below – the alphabetizing of the
names can be ignored as this is updated in the revised version you've provided.
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A few minor edits:
Co-chairs of the working groups should be identified
Consistency with MD or M.D.
Minor change to John Mellors
Thanks,
Ashley
From: Myles, Renate (NIH/OD) [E] <b>b6</b>
<b>Sent:</b> Friday, May 15, 2020 9:21 AM
To: Parker, Ashley (NIH/OD) [E] { b6 ; Collins, Francis (NIH/OD) [E] <b> </b>
Cc: Allen-Gifford, Patrice (NIH/OD) [E] b6 Wooldridge, Shannon (NIH/OD) [E]
b6 ; Pollock, Rachel (NIH/OD) [E] b6
Subject: RE: Time sensitive: Making your ACTIV Participation Public

APAR0000013162

Attached is the full list of members currently listed on the website in staging. I received the list from FNIH communications. Please let me know of any changes.
Thanks, Renate
From: Parker, Ashley (NIH/OD) [E] b6  Sent: Friday, May 15, 2020 9:11 AM  To: Myles, Renate (NIH/OD) [E] b6 Collins, Francis (NIH/OD) [E] b6  Cc: Allen-Gifford, Patrice (NIH/OD) [E] b6 ; Wooldridge, Shannon (NIH/OD) [E] b6  Subject: RE: Time sensitive: Making your ACTIV Participation Public
Hi Renate,
I've added the emails below but we have a major version control issues. I've been working with Cheryl to receive updates and did not have Sylvia Collins, Beth Bell and Jonathan Seals and apparently they are listed on a separate list the FNIH communications team is tracking.
We can send follow up emails to everyone except for those three – they will need to be contacted.
Moving forward, it may be best for you to receive updates from the communications team – FNIH is managing multiple spreadsheets one for the emails Cheryl is managing to schedule meetings and a separate list for the communications office.
Ralph Baric, Ph.D.  William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health  b6
Damon Deming, Ph.D. Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration  66
Greg Gatto, Ph.D.  Drug Development Regulatory Project Leader  RTI International  b6
Jay Grobler, Ph.D. Director, Infectious Disease Biology Merck & Co., Inc.  b6
Cat Lutz, Ph.D. Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center The Jackson Laboratory  b6

David Payne, Ph.D.
Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline
b6
<u> </u>
Louise Pitt, Ph.D.
Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases
<b>b6</b>
<u> </u>
Srinivas Rao, DVM, Ph.D.
Global Head, Translational In Vivo Models Global Research Platform
Sanofi
b6
<u>i</u>
Jay Rappaport, Ph.D.
Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center
b6
i
Frank Stegmeier, Ph.D.
Chief Scientific Officer
KSQ Therapeutics
<b>b6</b>
<u> </u>
Sylva Collins, Ph.D.
Director, Office of Biostatistics
Director, Office of Biostatistics
Director, Office of Biostatistics U.S. Food and Drug Administration
Director, Office of Biostatistics
Director, Office of Biostatistics U.S. Food and Drug Administration
Director, Office of Biostatistics U.S. Food and Drug Administration  6
Director, Office of Biostatistics U.S. Food and Drug Administration  b6  Judith Currier, M.D. Professor of Medicine
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Carlos Garner, Ph.D.
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Bill & Melinda Gates Foundation
b6
Kathrin Jansen, Ph.D.
Senior Vice President and Head of Vaccine Research and Development
Pfizer
b6
Antonio Lanzavecchia, M.D.
Senior Vice President and Senior Research Fellow
Vir Biotechnology, Inc.
Director, Institute for Research in Biomedicine, Bellinzona, Switzerland
<b>b6</b>
None at Research and P.
Nancy Messonnier, M.D.
Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention <b>b6</b>
Jonathan Seals, Ph.D.
Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority
hereneeneeneeneeneeneeneeneeneen
b6
From: Myles, Renate (NIH/OD) [E] b6
Sent: Friday, May 15, 2020 7:53 AM
To: Collins, Francis (NIH/OD) [E] b6
Cc: Allen-Gifford, Patrice (NIH/OD) [E] b6 Parker, Ashley (NIH/OD) [E]
b6   Wooldridge, Shannon (NIH/OD) [E]   b6   Pollock, Rachel (NIH/OD)
[E] b6
Subject: FW: Time sensitive: Making your ACTIV Participation Public

#### Hi Francis:

Below is the list of 23 vpeople who have not yet responded to your email. I cross referenced these names with the email list that Ashely sent and pulled addresses from that list. I didn't find emails for a number of these people, but I know there was a second round that went out using emails I don't have. Hoping Ashley can provide the missing emails.



#### Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

## Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration

## Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader RTI International

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Chair, AIDS Clinical Trial Group (ACTG)
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Director, TB & HIV Program
Bill & Melinda Gates Foundation
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Kathrin Jansen, Ph.D.
Senior Vice President and Head of Vaccine Research and Development
Pfizer
b6

#### Antonio Lanzavecchia, M.D.

Senior Vice President and Senior Research Fellow Vir Biotechnology, Inc.

Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

**b**6

## Nancy Messonnier, M.D.

Director, Center for the National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention

b6

#### Jonathan Seals, Ph.D.

Director, Strategic Science and Technology Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD) [E]	b6	}		
<b>Sent:</b> Thursday, May 14, 2020 11:00	AM			
To: Collins, Francis (NIH/OD) [E]	h.C			
Cc: Myles, Renate (NIH/OD) [E]	b6	Meltzer, Abbey (FNIH) [T]	b6	; Wholley, David
(FNIH) [T] <b>b6</b>				
Subject: Time sensitive: Making your	<b>ACTIV</b> Participat	tion Public		

**Subject.** Time sensitive, Making your ACTIV Participation Pub

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

Francis S. Collins, MD, PhD NIH Director Sent: 5/15/2020 5:37:36 PM To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr] CC: Allen-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense] Subject: RE: Time sensitive: Making your ACTIV Participation Public Renate - I do not see anything in FC's sent box, but perhaps it went out from someone else? Ashley may be able to confirm/offer more information. Rachel Pollock From: Myles, Renate (NIH/OD) [E] Sent: Friday, May 15, 2020 1:19 PM To: Pollock, Rachel (NIH/OD) [E] Cc: Allen-Gifford, Patrice (NIH/OD) [E] Parker, Ashley (NIH/OD) [E] ; Wooldridge, Shannon (NIH/OD) [E] b6 Subject: RE: Time sensitive: Making your ACTIV Participation Public Hi Rachel: Did another email go out this morning to the non-responders? From: Myles, Renate (NIH/OD) [E] Sent: Friday, May 15, 2020 8:13 AM To: Pollock, Rachel (NIH/OD) [E] Cc: Allen-Gifford, Patrice (NIH/OD) [E] Parker, Ashley (NIH/OD) [E] b6 Wooldridge, Shannon (NIH/OD) [E] Subject: RE: Time sensitive: Making your ACTIV Participation Public Thanks, Rachel. Jay Grobler just responded, so I've removed him from the list. Will you be sending it out this morning? From: Pollock, Rachel (NIH/OD) [E] Sent: Friday, May 15, 2020 8:08 AM To: Myles, Renate (NIH/OD) [E] Cc: Allen-Gifford, Patrice (NIH/OD) [E] Parker, Ashley (NIH/OD) [E] ; Wooldridge, Shannon (NIH/OD) [E] b6 Subject: RE: Time sensitive: Making your ACTIV Participation Public Renate - in case it is helpful, attached is what I believe to be the send round email, and which includes the full list of email addresses in the bcc line. CC'ing Ashley to confirm.

Pollock, Rachel (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4887CB3513E242DFA7D2DF712DCC6D6A-POLLOCKRC]

From:

Rachel Pollock			
O: b6			
C: <b>b6</b>			
From: Myles, Renate (NIH/OD) [E]	b6		
<b>Sent:</b> Friday, May 15, 2020 7:53 AM	<del>-</del>		
To: Collins, Francis (NIH/OD) [E]	b6		
Cc: Allen-Gifford, Patrice (NIH/OD) [E	b6	; Parker, Ashley (N	IIH/OD) [E]
Sent: Friday, May 15, 2020 7:53 AM  To: Collins, Francis (NIH/OD) [E]  Cc: Allen-Gifford, Patrice (NIH/OD) [E]  [E]  b6  [F]  b6  Subject: FW: Time sensitive: Making your	nannon (NIH/OD) [E]	b6	; Pollock, Rachel (NIH/OD)
[E] b6	\- <u></u>		
Subject: FW: Time sensitive: Making your	<b>ACTIV</b> Participation Pu	blic	
Hi Francis:			
Below is the list of 23 vpeople who have i	not yet responded to yo	our email. I cross referen	ced these names with the email
list that Ashely sent and pulled addresses	from that list. I didn't f	find emails for a number	of these people, but I know
there was a second round that went out u	using emails I don't hav	e. Hoping Ashley can pro	ovide the missing emails.
	<b>b</b> 6		
		•	

#### Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

## Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration

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# Srinivas Rao, DVM, Ph.D. Global Head, Translational In Vivo Models Global Research Platform Sanofi Jay Rappaport, Ph.D. Professor of Microbiology and Immunology Director and Chief Academic Officer Tulane University National Primate Research Center Frank Stegmeier, Ph.D. Chief Scientific Officer **KSQ Therapeutics** Sylva Collins, Ph.D. Director, Office of Biostatistics U.S. Food and Drug Administration Judith Currier, M.D. Professor of Medicine University of California Los Angeles Division of Infectious Diseases Chair, AIDS Clinical Trial Group (ACTG) **b6** John Farley, M.D., M.P.H. Director, Office of Infectious Diseases Center for Drug Evaluation and Research U.S. Food and Drug Administration b6 Elliot Levy, M.D. Senior Vice President, Global Development Amgen b6 Lionel Bascles, Ph.D. Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi b6 Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company b6

Peter Stein, M.D.

Director of Office of New Drugs

b6

Center for Drug Evaluation and Research U.S. Food and Drug Administration

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Emilio Emini, Ph.D. Director, TB & HIV Program Bill & Melinda Gates Foundation  b6	
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Pfizer <b>b6</b>	
Antonio Lanzavecchia, M.D. Senior Vice President and Senior Research Fellow Vir Biotechnology, Inc. Director, Institute for Research in Biomedicine, Belli	nzona, Switzerland
Nancy Messonnier, M.D.  Director, Center for the National Center for Immuniz Centers for Disease Control and Prevention  b6	zation and Respiratory Diseases
Jonathan Seals, Ph.D.	
Director, Strategic Science and Technology Biomedical Advanced Research and Development A	uthority
Director, Strategic Science and Technology	Meltzer, Abbey (FNIH) [T] <b>b6</b> ; Wholley, David
Director, Strategic Science and Technology Biomedical Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research Advanced Research and Development Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Resea	Meltzer, Abbey (FNIH) [T] <b>b6</b> ; Wholley, David
Director, Strategic Science and Technology Biomedical Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Research Advanced Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research Research	Meltzer, Abbey (FNIH) [T] <b>b6</b> ; Wholley, David
Biomedical Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research and Development Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Advanced Research Research Advanced Research Advanced Research Research Research Research Research Research Research	Meltzer, Abbey (FNIH) [T] b6 ; Wholley, David ation Public  ide stakeholders with a central resource for information about our and new developments. Currently, the content is based on publicly TIV leadership and working group members. Your representation on rtise and experience from all sectors committed to this effort. Please bbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow,

Beth Bell, M.D., MPH

Francis S. Collins, MD, PhD

NIH Director

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]

**Sent**: 5/15/2020 5:53:09 PM

To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]

CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]

**Subject**: RE: Time sensitive: Making your ACTIV Participation Public **Attachments**: RE: Time sensitive: Making your ACTIV Participation Public

Sent this morning – please see attached.

From: Myles, Renate (NIH/OD) [E] **b6** 

Sent: Friday, May 15, 2020 1:51 PM

To: Parker, Ashley (NIH/OD) [E] Cc: Brodd, Lauren (NIH/OD) [E]

Subject: FW: Time sensitive: Making your ACTIV Participation Public

Hi Ashley:

Do you have the emails for those missing emails? I can reply all to the original email and ask again.

#### Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

## Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration

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Vice President & Head, Medicine Opportunities Research Unit GlaxoSmithKline

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Tulane University National Primate Research Center

#### Frank Stegmeier, Ph.D.

Chief Scientific Officer KSQ Therapeutics

#### John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases

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U.S. Food and Drug Administration
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Amgen
b6
<u></u> ;
Lionel Bascles, Ph.D.
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Sanofi
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Carlos Garner, Ph.D.
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Eli Lilly and Company
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Nancy Messonnier, M.D.
Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
b6
From: Parker, Ashley (NIH/OD) [E] b6
Sent: Friday, May 15, 2020 10:35 AM
To: Myles, Renate (NIH/OD) [E]  Co: Brodd Lauren (NIH/OD) [E]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Sylva, Beth and Jonathan – how will we handle getting their permissions? From: Myles, Renate (NIH/OD) [E] b6 Sent: Friday, May 15, 2020 10:33 AM To: Parker, Ashley (NIH/OD) [E] **b6** Cc: Brodd, Lauren (NIH/OD) [E] Subject: RE: Time sensitive: Making your ACTIV Participation Public Thanks, Ashley and Lauren. Very helpful. From: Parker, Ashley (NIH/OD) [E] Sent: Friday, May 15, 2020 10:27 AM To: Myles, Renate (NIH/OD) [E] **b6** Cc: Brodd, Lauren (NIH/OD) [E] Subject: RE: Time sensitive: Making your ACTIV Participation Public Hi Renate, Sparing FC's inbox and others. With many thanks to Lauren for helping us with this. Please see edits attached and below – the alphabetizing of the names can be ignored as this is updated in the revised version you've provided. A few minor edits: Co-chairs of the working groups should be identified Consistency with MD or M.D. Minor change to John Mellors Thanks, **Ashley** From: Myles, Renate (NIH/OD) [E] Sent: Friday, May 15, 2020 9:21 AM To: Parker, Ashley (NIH/OD) [E] Collins, Francis (NIH/OD) [E] Cc: Allen-Gifford, Patrice (NIH/OD) [E] Wooldridge, Shannon (NIH/OD) [E] ; Pollock, Rachel (NIH/OD) [E] Subject: RE: Time sensitive: Making your ACTIV Participation Public Hi Ashley: Attached is the full list of members currently listed on the website in staging. I received the list from FNIH communications. Please let me know of any changes. Thanks, Renate From: Parker, Ashley (NIH/OD) [E] Sent: Friday, May 15, 2020 9:11 AM To: Myles, Renate (NIH/OD) [E] [ ኘ; Collins, Francis (NIH/OD) [E] ; Wooldridge, Shannon (NIH/OD) [E] Cc: Allen-Gifford, Patrice (NIH/OD) [E]

Have you hear back from others? How many people are missing now?

<b>b6</b> ; Pollock, Rachel (NIH/OD) [E] <b>b6</b>
Subject: RE: Time sensitive: Making your ACTIV Participation Public
Hi Renate,
I've added the emails below but we have a major version control issues. I've been working with Cheryl to receive updates and did not have Sylvia Collins, Beth Bell and Jonathan Seals and apparently they are listed on a separate list the FNIH communications team is tracking.
We can send follow up emails to everyone except for those three – they will need to be contacted.
Moving forward, it may be best for you to receive updates from the communications team — FNIH is managing multiple spreadsheets one for the emails Cheryl is managing to schedule meetings and a separate list for the communications office.
Ralph Baric, Ph.D.
William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health
b6
Damon Deming, Ph.D.
Virologist, Division of Antiviral Products, Office of New Drugs
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Greg Gatto, Ph.D.
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Jay Grobler, Ph.D.
Director, Infectious Disease Biology
Merck & Co., Inc.
<b>b6</b>
Cat Lutz, Ph.D.
Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center
The Jackson Laboratory
b6
David Payma, Dk D
David Payne, Ph.D.  Vice President & Head, Medicine Opportunities Research Unit
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<b>Srinivas Rao, DVM, Ph.D.</b> Global Head, Translational In Vivo Models Global Research Platform
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Carlos Garner, Ph.D.
Vice President, Global Regulatory Affairs
Eli Lilly and Company
b6

# Peter Stein, M.D.

Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration

b6
Beth Bell, M.D., MPH
Clinical Professor, Global Health
University of Washington
<u>b6</u>
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b6
<u></u>
Nancy Messonnier, M.D.
Director, Center for the National Center for Immunization and Respiratory Diseases  Centers for Disease Control and Prevention
b6
Jonathan Seals, Ph.D.
Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority
b6
From: Myles, Renate (NIH/OD) [E] <b>b6</b>
Sent: Friday, May 15, 2020 7:53 AM
To: Collins, Francis (NIH/OD) [E] b6
Cc: Allen-Gifford, Patrice (NIH/OD) [E]       b6       ; Parker, Ashley (NIH/OD) [E]         b6       ; Wooldridge, Shannon (NIH/OD) [E]       b6       ; Pollock, Rachel (NIH/OD)
b6 ; Wooldridge, Shannon (NIH/OD) [E] b6 ; Pollock, Rachel (NIH/OD)
[E] <u>b6</u>
Subject: FW: Time sensitive: Making your ACTIV Participation Public
Hi Francis:
Below is the list of 23 vpeople who have not yet responded to your email. I cross referenced these names with the email
list that Ashely sent and pulled addresses from that list. I didn't find emails for a number of these people, but I know
there was a second round that went out using emails I don't have. Hoping Ashley can provide the missing emails.
<b>b6</b>
NU

### Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

## Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration

## Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader RTI International

# Jay Grobler, Ph.D.

Director, Infectious Disease Biology Merck & Co., Inc.

## Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center The Jackson Laboratory

## David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit GlaxoSmithKline

### Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences United States Army Medical Research Institute of Infectious Diseases

# Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform Sanofi

# Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology Director and Chief Academic Officer Tulane University National Primate Research Center

# Frank Stegmeier, Ph.D.

Chief Scientific Officer KSQ Therapeutics

## Sylva Collins, Ph.D.

Director, Office of Biostatistics U.S. Food and Drug Administration

## Judith Currier, M.D.

Professor of Medicine University of California Los Angeles Division of Infectious Diseases Chair, AIDS Clinical Trial Group (ACTG)

b6

John Farley, M.D., M.P.H.
Director, Office of Infectious Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
b6
Filiat Laure RA D
Elliot Levy, M.D.
Senior Vice President, Global Development
Amgen be
<u>b6</u>
Lionel Bascles, Ph.D.
Senior Vice President, Global Head of Clinical Sciences & Operations
Sanofi
b6
Carlos Garner, Ph.D.
Vice President, Global Regulatory Affairs
Eli Lilly and Company
b6
Peter Stein, M.D.
Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
b6
Ld
Beth Bell, M.D., MPH
Clinical Professor, Global Health
University of Washington
Emilio Emini, Ph.D.
Director, TB & HIV Program
Bill & Melinda Gates Foundation
b6
Kathrin Janean Ph D
Kathrin Jansen, Ph.D. Senior Vice President and Head of Vaccine Research and Development
Pfizer
b6
<u>L</u>
Antonio Lanzavecchia, M.D.
Senior Vice President and Senior Research Fellow
Vir Biotechnology, Inc.
Director, Institute for Research in Biomedicine, Bellinzona, Switzerland
b6
Nancy Messonnier, M.D.
Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
b6

### Jonathan Seals, Ph.D.

Director, Strategic Science and Technology Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD) [E]	b6			
<b>Sent:</b> Thursday, May 14, 2020 11:00 AM				
To: Collins, Francis (NIH/OD) [E]	<b>^6</b>	·		
<b>Cc:</b> Myles, Renate (NIH/OD) [E] ∢	06	; Meltzer, Abbey (FNIH) [T]	b6	; Wholley, David
(FNIH) [T] <b>b6</b>		i		i
Subject: Time sensitive: Making your ACTI	V Participa	tion Public		

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

Francis S. Collins, MD, PhD NIH Director

From:	Adam, Stacey (FNIH) [T] [, (FYDIBOHF23SPDLT)/CN=	•					
Sent:	5/15/2020 7:18:50 PM	NECH IENTS/CN-DCD	373100730400	75210110100545	717 ADAM557		
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	b6	Eric Hughes	b6		ge, Lisa M	b6	
	Sandeep Menon	b6	Proschan,	Michael (NIH/NI		b6	
	Read, Sarah (NIH/NIAID)			onne (FDA/CDER)	,		]; Rubin,
	Daniel B. (FDA/CDER)	b6		(FDA/CDER)	b6		en Lynn
	Price		b6				
	[	b6			Eron, Joe		
	b6 ; Ja	van, Arzhang (NIH/NI	AID) [E] :	b6	]; Roa, Jhoanna	b6	}
		eter (NIH/NIAID) [E][	b6		.i '		
CC:	Demarcus b6	Tounta	s, Karen (FNIH)	[T] <b>b6</b>	; Wachtel,	Jonathan	
	[jwachtel@deloitte.com];	Elizabeth Kim [elkim	@deloitte.com	; Parker, Ashley	(NIH/OD) [E]		
	[/o=ExchangeLabs/ou=Exc	change Administrative	e Group				
	(FYDIBOHF23SPDLT)/cn=F	Recipients/cn=306b22	.44466140faa9	5aaaafe06ebd70	-parkeras]; Jhoanr	ia Roa	
	b6	Eron, Joseph J Jr		3 ); 5	Smith, David		
	NU	Paul Klekotka	b6	; Ajay N	irula ( <b>b6</b>		
Subject:	ACTIV TX-Clinical Master Protocol Outpatient mAbs Writing Team Meeting #1						
Attachments:	a5401-d03-activ-051620.						
Location:	<u> </u>	b6			j		
Start:	5/18/2020 5:00:00 PM						
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Required	Judy Currier; Eric Hughes;	Lisa LaVange; Sande	ep Menon; Pros	schan, Michael (N	IIH/NIAID) [E]; Rea	id, Sarah	
Attendees:	(NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price,						
			b6				
	<u> </u>	b6	jı; Er	on, Joe; Javan, A	rzhang (NIH/NIAIC	) [E]; Roa,	Jhoanna
	<b>b6</b> ; Kim, Pe	eter (NIH/NIAID) [E]					
Optional	Demarcus; Tountas, Karer	n (FNIH) [T]; Wachtel,	Jonathan; Eliza	beth Kim; Parker	, Ashley (NIH/OD)	[E]; Jhoan	na Roa;
Attendees:	Eron, Joseph J Jr; Smith, D	avid; Paul Klekotka					

***Updated with New Protocol Version***

Dear ACTIV-2 Master Protocol Writing Team,

Thank you all for being willing to get together so quickly. I look forward to the ACTIV and the ACTG teams working together to make this protocol great and get it going quickly.

We will work to get a full list of participants and their roles together for this meeting to distribute. In the meantime, the ACTG team has been kind enough to send the current draft of their protocol for us to start from. They have noted to me that they have removed some agent specific information for confidentiality purposes, but all else should be ready for this group to review and start thinking and commenting on.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/15/2020 7:21:08 PM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner ; Eric Hughes ; Keith Gottesdiener LaVange, Lisa M **b6** ; Amanda Peppercorn ; Proschan, Michael Menon (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn ; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael ; Wung, Peter /US <u>b6</u>; Karen Lynn Price b6 ; Patterson, Amy (NIH/NHLBI) [E] j Pamela Tenaerts, M.D. [/o=ExchangeLabs/ou=Exchange Administrative Group" (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group Beumont-Mauviel, Maria [JRDUS] b6; Peeters, Monika [JRDBE] Woodfall, Brian [JRDUS] b6; Van Heeswijk, Rolf [JRDBE] (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy b6 ); Demarcus b6 ; Macone, Erin CC: Mary Biggs Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina b6 Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc) ACTIV TX-Clinical Master Protocol Subgroup Meeting #19 Subject: Location: Start: 5/20/2020 5:00:00 PM End: 5/20/2020 6:00:00 PM Show Time As: Tentative

APAR0000017172-2443767

Required Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo Attendees: (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda

Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters,

Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]

Optional Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley

Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

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Show Time As: Tentative

Required Attendees:

Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters,

Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]

Optional Attendees:

Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley

es: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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То:	Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS
	[E] b6 ; Butterton, Joan b6 ; Judy Currier
	b6 ; Eric Hughes b6 ; LaVange, Lisa M b6
	Read, Sarah (NIH/NIAID) [E] b6 Karen Lynn Price b6 Higgs, Elizabeth (NIH/NIAID) [E] b6 Woodcock, Janet (FDA/CDER) b6 /]; Stein, Peter
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CC.	b6 ; Marks, Gilbert (OS/ASPR/BARDA) (CTR) b6
CC:	Demarcus b6 Tountas, Karen (FNIH) [T] Wacntel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject:	ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review
-	5401 Protocol Synopsis 051920v3.docx
Location:	[
Location.	b6
Start:	5/20/2020 5:00:00 PM
End:	5/20/2020 6:00:00 PM
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Attendees: Optional Attendees:	Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR) Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]
Dear ACTIV	TX-Clinical Master Protocol mAbs Steering Committee,
assembled by	ttached the synopsis of the outpatient protocol for review at our meeting today. This was y the ACTG group based on our writing team conversations and then edited a bit by Lisa and Karentical sections.
	ent is NOT ready to share beyond this group yet, but could be gotten ready in short turn if needed any summit, Janet. We will just need to know when that is.
Finally, we v	vill be discussing the selection of the inpatient network for the companion protocol today.
Thanks,	
Stacey	
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/15/2020 7:21:21 PM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner Keith Gottesdiener **b6** ]; LaVange, Lisa M **b6** b6 Keith Gottesdiener ; Eric Hughes ; Elliott Levy **b6** ; Sandeep ; Amanda Peppercorn Menon ; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn ; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael ; Wung, Peter /US <u>b6</u> ; Karen Lynn Price Pamela Tenaerts, M.D. <u>b6</u> ; Patterson **b**6 ; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy Beumont-Mauviel, Maria [JRDUS] b6 Peeters, Monika [JRDBE]
Woodfall, Brian [JRDUS] b6 Van Heeswijk, Rolf [JRDBE] b6 b6 Demarcus b6 Macone, Erin CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina \$ Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc] ACTIV TX-Clinical Master Protocol Subgroup Meeting #20 Subject: Location: Start: 5/22/2020 6:00:00 PM End: 5/22/2020 7:00:00 PM Show Time As: Tentative

Required Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo Attendees: (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda

Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters,

Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]

Optional Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley

Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Stacey Adam is inviting you to a scheduled Zoom meeting.

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]; LaVange, Lisa M b6 ; Elliott Levy b

6 ; Amanda Peppercorn b6

angel abs/our-tychange Administrative (Spour ; Sandeep b6 Menon Proschan, Michael (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn ; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Vincent, Michael b6 ; Wung, Peter /US b6 ; Karen Lynn Price
b6 Pamela Tenaerts, M.D. b6 Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy Beumont-Mauviel, Maria [JRDUS] <u>b6</u>, Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS] <u>b6</u>, Van Heeswijk, Rolf [JRDBE] Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Bharucha_David Gavin, Brian <u>b6</u>; Sadeh, Jonathan; Harler, Mary Beth **b6**; Goff, E Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc] Mary Biggs b6 ; Demarcus b6 ; Macone, Erin CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina ; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Melsheimer, Rich [CNTNL] Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #20

ACTIV_Therapeutics Clinical Master Protocol Sub Group_22May2020 Meeting Guide.pdf; Agenda capture 1.PNG Attachments: Location: b6 5/22/2020 6:00:00 PM Start: End: 5/22/2020 6:30:00 PM Show Time As: Busy Required Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo Attendees: (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]; Brown, Jeremy (NIH/NINDS) [E]; Bharucha_David; Gavin, Brian; Sadeh, Jonathan; Harler, Mary Beth Optional Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Melsheimer, Rich [CNTNL] Dear ACTIV TX-Clinical Master Protocol Subgroup, Thanks for your understanding.

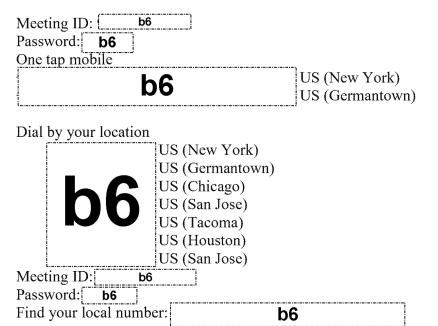
For this meeting today, we have decide to split this meeting into two meetings to make most efficient use of everyone's time. This first 30 minute meeting will be the entire group with the companies for ACTIV-1 to discuss the next steps for this protocol. The second 30 minutes will now become a meeting of the mAb Steering Committee to finalize some decisions for the ACTIV-2 protocol that need to be completed by EOD today.

Please find attached the slides for this first meeting today.

Thanks, Stacey

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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	5/15/2020 7:24:01 PM
To:	Eric Hughes b6 ; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa];
	Ruxandra Draghia-Akli h6 : Mellors, John W [/o=Fxchangel abs/ou=Fxchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel <b>b6</b> ; Colvis,
	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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	b6 ; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];
	Vincent, Michael b6 ; Keith Gottesdiener b6 ; Elliott Levy
	b6 ; Wung, Peter /US b6 Koroshetz, Walter (NIH/NINDS) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner
	b6 ; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	Maria [rosalvarez@deloitte.com]; Salathin, Carla b6
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
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	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	b6 ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject:	ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #11
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Start: End:	5/19/2020 5:00:00 PM 5/19/2020 6:00:00 PM
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Required	Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine
Attendees:	(NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR);
	Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs,
	Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla;
Attendees:	Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula
	(NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] b6
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	b6 ; Read, Sarah (NIH/NIAID) [E] b6 Ruxandra Draghia-Akli
	b6 ; Mellors, John W b6 ; Naimish Patel b6 Colvis,
	Christine (NIH/NCATS) [E] b6 Young, John b6 Stein, Peter
	(FDA/CDER) b6 ]; Poole, Mike b6 Buchman, Tim
	(OS/ASPR/BARDA) (CTR) <b>b6</b> Vincent, Michael <b>b6</b> ; Keith
	Gottesdiener b6 ; Elliott Levy b6 ; Wung, Peter / US
	b6 ; Koroshetz, Walter (NIH/NINDS) [E] b6 ; Higgs, Elizabeth (NIH/NIAID) [E] b6 ; Carlos O Garner b6 ; Goff, David (NIH/NHLBI) [E]
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] b6 ; Alvarez, Rosa Maria
	[rosalvarez@deloitte.com]; Salathin, Carla b6   Parker, Ashley (NIH/OD)
	[L] [/o-Exchange Laby/ou-Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
	b6 Melencio, Cheryl (FNIH) [T] b6 Lucas Smalldon
	b6 ; Walker, Paula (NIH/NINDS) [E] b6 ; Ward, Jackie
	(NIH/NINDS) [E] b6 ; Rose Li Central Account [FNIH@roseliassociates.com]; b6
Subject:	ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #11
Attachments:	Therapeutic information request form-v9-clean.docx; ACTIV_Therapeutics Clinical Agent Prioritization Sub
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Location:	b6
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Start:	5/19/2020 5:00:00 PM
End:	5/19/2020 6:00:00 PM
Show Time As:	Busy
Required	Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine
Attendees:	(NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR);
, te contracto.	Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs,
	Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; <b>b6</b>
Attendees:	Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula
	(NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] <b>b6</b> ; Rose Li Central Account
	<u> </u>
Dear ACTIV TX	K-Clinical Agent Prioritization Subgroup,
Please find at	tached the materials for tomorrow's call.
1. Slides	with topics and agenda internal.
	ted Company RFI/Survey for final review.
Thanks,	
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Judey	
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	Ruxandra Draghia-Akli <b>b6</b> ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel   <b>b6</b> ; Colvis,
	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John
	b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike
	b6 ; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange
	$Administrative\ Group\ (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];$
	Vincent, Michael <b>b6</b> ; Keith Gottesdiener <b>b6</b> ; Elliott Levy
	<b>b6</b> ; Wung, Peter /US <b>b6</b> ; Koroshetz, Walter (NIH/NINDS) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner    b6
	b6 ; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
CC.	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	Maria [rosalvarez@deloitte.com]; Salathin, Carla <b>b6</b>
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	<b>b6</b> Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Cubicat	ACTIVITY Clinical Agent Prioritization Subgroup Mosting #12
Subject: Location:	ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12  b6
Location.	j
Start:	5/21/2020 3:00:00 PM
End:	5/21/2020 4:00:00 PM
Show Time As:	
Required	Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine
Attendees:	(NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR);
	Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs,
	Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; b6
Attendees:	Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula
	(NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] <b>b6</b>
Stoory A dam	is inviting you to a schoduled Zeem meeting
Stacey Adam	is inviting you to a scheduled Zoom meeting.
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Join Zoom M	
	b6

Meeting ID: b6 Password: **b6** One tap mobile US (Chicago) b6 US (New York) Dial by your location US (Chicago) US (New York) US (Germantown)
US (San Jose) US (San Jose) US (Tacoma) US (Houston) Meeting ID: Password: **b6** Find your local number: b6

From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]			
Sent:	(FIDIBOHE235PDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/15/2020 7:24:08 PM			
To:	Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes			
	b6 ; Read, Sarah (NIH/NIAID) [E] b6 ; Ruxandra Draghia-Akli			
	b6 ; Mellors, John W b6 ; Naimish Patel b6 ; Colvis,			
	Christine (NIH/NCATS) [E] b6 ; Young, John b6 ; Stein, Peter			
	(FDA/CDER) <b>b6</b> ; Buchman, Tim			
	(OS/ASPR/BARDA) (CTR) <b>b6</b> Vincent, Michael <b>b6</b> Keith			
	Gottesdiener b6 ; Elliott Levy b6 ; Wung, Peter /US			
	b6 ; Koroshetz, Walter (NIH/NINDS) [E] b6 ; Higgs, Elizabeth			
	(NIH/NIAID) [E] b6 ; Carlos O Garner b6 ; Goff, David (NIH/NHLBI) [E]			
CC:	b6   Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T]   b6   ; Alvarez, Rosa Maria			
CC.	[rosalvarez@deloitte.com]; Salathin, Carla <b>b6</b>			
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]			
	b6 ; Melencio, Cheryl (FNIH) [T] b6 ; Lucas Smalldon			
	b6 ; Walker, Paula (NIH/NINDS) [E] b6 ; Ward, Jackie			
	(NIH/NINDS) [E] <b>b6</b> Rose Li Central Account [FNIH@roseliassociates.com]			
	<u> </u>			
Subject:	ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12			
Attachments:	2020-05-19_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting-Summary.pdf; ACTIV_Therapeutics Clinical			
	Agent Prioritization Sub Group_21May2020 Meeting Guide.pdf			
Location:	b6			
Start:	5/21/2020 3:00:00 PM			
End:	5/21/2020 4:00:00 PM			
Show Time As:				
Required	Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine			
Attendees:	(NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR);			
	Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs,			
	Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]			
Optional	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; <b>b6</b>			
Attendees:	Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula			
	(NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] <b>b6</b> ; Rose Li Central Account			
D TV Cl' :				
Dear IX-Clinic	cal Agent Prioritization Subgroup,			
DI 6: 1 11				
	tached the formal summary from yesterday's meeting.			
	lease find the slides for tomorrow's meetings. Please let me know if you have any amendments or			
additions.				
Thanks,				
Stacey				
Join Zoom Meeting				
b6				
t				
Meeting ID:	b6			
Password:	b6			

Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/15/2020 7:27:04 PM Sent: To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra b6 ; Eisner, Mark b6 ; Gottesdiener, Keith b6 ; Hughes, Eric b6 ; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa b6 ; Levy, Elliot b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep b6 ; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn b6 ; Garner, Carl b6 ; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy ; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey) CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy

b6 ; Jansen, Kathrin b6 ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group b6 ; Biggs, Mary b6 ; Butcher, Tina b6

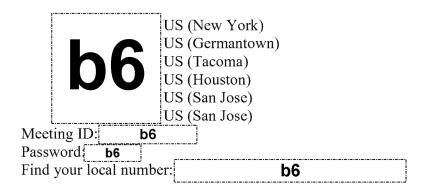
Demarcus b6 Macone, Erin b6 Melencio, Cheryl (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIROHE23SPDLT)/cn=Position (FNIH) (FNIH) (FNIH) (FYDIROHE23SPDLT)/cn=Position (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNIH) (FNI (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla

; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
	[jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];
	Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
	Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio <b>b6</b> ; Rose
	Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas
	Smalldon b6 ; Stratton, Benjamin [bstratton@DELOITTE.com];
	b6 ; Mollica, Linda /US b6 ; Qashu, Felicia (NIH/OD) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
	(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER)
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]
	ACTIVITY OF COLUMN 11 OF TAX 12 117
Subject:	ACTIV TX-Clinical Working Group Meeting #7
Location:	b6
Start:	5/21/2020 6:00:00 PM
End:	
	5/21/2020 7:00:00 PM
Show Time As:	rentative
Attendees:  Optional Attendees:	Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E] Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; b6 Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] Rubin, Daniel B.
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L	US (New York)
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/15/2020 7:27:06 PM Sent: To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra b6 Eisner, Mark b6 Gottesdiener, Keith b6 Hughes, Eric b6 Judy Currier JoeExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa b6 }; Levy, Elliot b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep b6 ; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange  $Administrative \ \ Group \ (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140 faa95aaaafe06ebd70-parkeras];$ b6 Peppercorn, Amanda b6 Poole, Mike ; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy ; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy ; Jansen, Kathrin **b6** Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDL1)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.nj; Young, John
	<b>b6</b> ]; Biggs, Mary <b>b6</b> ; Butcher, Tina <b>b6</b> ;
	Demarcus <b>b6</b> ; Macone, Erin <b>b6</b> ; Melencio, Cheryl (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
	b6 ; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
	· · · · · · · · · · · · · · · · · · ·
	[jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];
	Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio <b>b6</b> Rose
	Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas
	Smalldon b6 ; Stratton, Benjamin [bstratton@DELOITTE.com];
	b6 Mollica, Linda /US b6 ; Qashu, Felicia (NIH/OD) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
	(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER)
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]
Subject:	ACTIV TX-Clinical Working Group Meeting #7
Attachments:	ACTIV Therapeutics-Clinical Full Working Group 21May2020 Meeting Guide.pdf
Location:	b6
	\
Start:	5/21/2020 6:00:00 PM
End:	5/21/2020 7:00:00 PM
Show Time As:	Busy
Required	Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner,
Attendees:	Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John;
Attenuees.	
	Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael;
	Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH)
	[T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs,
	Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E];
	Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen
	(NIH/OD) [E]
Optional	Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas
Attendees:	(NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla;
	Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman,
	Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon;
	Stratton, Benjamin; <b>b6</b> Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy
	(NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] <b>b6</b> ; Rubin, Daniel B. (FDA/CDER)
Dear ACTIV T	K-Clinical WG,
ooking forwa	ard to seeing you all soon at the meeting. Please find attached the slides for the meeting.
LOCKING TOTAL	aru to seeing you an soon at the meeting. Flease info attached the shoes for the meeting.

Thanks, Stacey

APAR0000019850

Join Zoom Meeting	
	b6
Meeting ID: <b>b6</b>	
Password: b6	
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b6	US (Chicago) US (New York)
Dial by your location	
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US (New York)	
US (Germantown) US (Tacoma) US (Houston)	
US (Tacoma)	
US (Houston)	
US (San Jose)	
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Meeting ID: b6	
Password: <b>b6</b>	
Find your local number: <b>b</b>	6

From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]			
Sent:	5/16/2020 2:58:42 AM			
To:	Eric Hughes b6; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange			
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa];			
	Ruxandra Draghia-Akli b6; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative			
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel <b>b6</b> ; Colvis,			
	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John			
	b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike			
	b6 ; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange			
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];			
	Vincent, Michael b6 ; Keith Gottesdiener b6 ; Elliott Levy			
	b6 ; Wung, Peter /US b6 ; Koroshetz, Walter (NIH/NINDS) [E]			
	[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth			
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner			
	b6 ; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]			
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative			
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa			
	Maria [rosalvarez@deloitte.com]; Salathin, Carla <b>b6</b>			
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]			
	[/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon			
	b6 ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange			
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];			
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Dana Carluccio			
	<b>b6</b> Rose Li Central Account [FNIH@roseliassociates.com]			
Subject:	Second Follow-up from ACTIV TX-Clinical Agent Prioritization Subgroup #10			
Attachments:	2020-05-14_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting Summary.pdf; Therapeutic information			
	request form-v8.docx			
Dear ACTIV T	X-Clinical Agent Prioritization Subgroup,			
Please find at	tached the formal summary from the call yesterday.			
	with the control of the profession and the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control			
	am attaching the most current version of the RFI/Survey. Reminder if you have any suggestions please			
email me. W	e could particularly use help on the neutralizing mAbs section.			
Thanks,				
Stacey				
634 8 4 3	**************************************			
Stacey J. Ad				
Director, Cancer Research Partnerships				
/				
Direct:	b6 Mobile: b6			

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/16/2020 3:34:48 AM Sent: To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, b6; Eisner, Markb6; Gottesdiener, Keith; Hughes, Ericb6; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa b6 ; Levy, Elliot b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep **b6**; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish b6 ; Peppercorn, Amanda b6 Poole, Mike Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn **b6** ; Garner, Carl **b6** ; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy ; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy ; Jansen, Kathrin **b6** Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla ; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
	[jwachtel@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa [rosalvarez@deloitte.com];
	Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [ b6 ; Rose
	Li Central Account [FNIH@roseliassociates.com]; Anderson, Margaret [marganderson@deloitte.com]; Lucas
	Smalldon b6 ; Stratton, Benjamin [bstratton@DELOITTE.com];
	b6 Mollica, Linda /US b6 ; Qashu, Felicia (NIH/OD) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
	(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER)
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]
Subject:	Follow-up from ACTIV TX-Clinical Working Group #6
Attachments:	2020-05-14_TX-Clinical_WG_Meeting_Summary.pdf
Dear TX-Clinio	cal Working Group,
Please find at	ttached the formal summary of our meeting yesterday. Don't hesitate to contact me if you have additional
	nts that need to be made.
Thanks,	
Stacey	
Stacey	
	2 XV2 VA
Stacey J. Ad	·
Director, Car	
Research Par	
Direct:	<b>b6</b>   Mobile: <b>b6</b>

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF] Sent: 5/16/2020 2:34:05 PM To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr] CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Allen-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]; Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj] RE: Time sensitive: Making your ACTIV Participation Public Subject: Didn't get to this last night. Any change in the plan now? Francis From: Myles, Renate (NIH/OD) [E] Sent: Friday, May 15, 2020 3:53 PM To: Collins, Francis (NIH/OD) [E] b6 Cc: Parker, Ashley (NIH/OD) [E] Allen-Gifford, Patrice (NIH/OD) [E] }; Burklow, John (NIH/OD) [E] b6 ; Pollock, Rachel (NIH/OD) [E] b6 Subject: RE: Time sensitive: Making your ACTIV Participation Public That's fine. We still haven't pushed the page live. We can do it Monday morning, which gives people time over the weekend to respond. We'll remove the names of the people who do not respond by Monday morning. From: Collins, Francis (NIH/OD) [E] b6 Sent: Friday, May 15, 2020 3:51 PM To: Myles, Renate (NIH/OD) [E] b6 Cc: Parker, Ashley (NIH/OD) [E] Allen-Gifford, Patrice (NIH/OD) [E] { Pollock, Rachel (NIH/OD) [E] { Burklow, John (NIH/OD) [E] b6 b6 Subject: RE: Time sensitive: Making your ACTIV Participation Public I will do, but can't get to it until 4:30 From: Myles, Renate (NIH/OD) [E] Sent: Friday, May 15, 2020 3:48 PM To: Collins, Francis (NIH/OD) [E] **b6** Cc: Parker, Ashley (NIH/OD) [E] Allen-Gifford, Patrice (NIH/OD) [E] ; Burklow, John (NIH/OD) [E] b6 ; Pollock, Rachel (NIH/OD) [E] b₆ Subject: FW: Time sensitive: Making your ACTIV Participation Public Hi Francis:

The below individuals have not yet responded. Do you want to send out another email to them? There are 18 individuals. You'll need to delete the names below and cut and paste their emails in the bcc. Let me know if you'd like

of this string.
Thanks, Renate
<b>b6</b>
Ralph Baric, Ph.D.
William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health
Damon Deming, Ph.D.
Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration <b>b6</b>
Jay Grobler, Ph.D.
Director, Infectious Disease Biology
Merck & Co., Inc.
David Payne, Ph.D.
Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline
b6
Louise Pitt, Ph.D.
Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases
b6
Srinivas Rao, DVM, Ph.D.
Global Head, Translational In Vivo Models Global Research Platform
Sanofi
b6
Jay Rappaport, Ph.D.
Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center
b6

Frank Stagmaiar, Ph.D.
Frank Stegmeier, Ph.D. Chief Scientific Officer
KSQ Therapeutics
<b>b6</b>
Judith Currier, M.D.
Professor of Medicine
University of California Los Angeles
Division of Infectious Diseases
Chair, AIDS Clinical Trial Group (ACTG)
b6
John Forlov, M.D. M.D. U
John Farley, M.D., M.P.H.
Director, Office of Infectious Diseases  Contar for Drug Evaluation and Research
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
b6
Elliot Levy, M.D.
Senior Vice President, Global Development
Amgen
b6
Lional Bassles Blo D
Lionel Bascles, Ph.D.
Senior Vice President, Global Head of Clinical Sciences & Operations
Sanofi
<b>b6</b>
Carlos Garner, Ph.D.
Vice President, Global Regulatory Affairs
Eli Lilly and Company
b6
Dates Chair AA D
Peter Stein, M.D.
Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
<b>b6</b>
Emilio Emini, Ph.D.
Director, TB & HIV Program
Bill & Melinda Gates Foundation
b6
Kathrin Jansen, Ph.D.
Senior Vice President and Head of Vaccine Research and Development
Pfizer
b6
Antonio Lanzavecchia, M.D.
Senior Vice President and Senior Research Fellow

Vir Biotechnology, Inc.

Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

b6		
Nancy Messo	nnier. M.D.	
,	- /	tional Center for Immunization and Respiratory Disease
Centers for D	isease Contro	l and Prevention
b6		

From: Collins, Francis (NIH/OD) [E]	b6			
Sent: Thursday, May 14, 2020 11:00 AM				
To: Collins, Francis (NIH/OD) [E]	b6			
Cc: Myles, Renate (NIH/OD) [E]	DO	; Meltzer, Abbey (FNIH) [T]	b6	; Wholley, David
(FNIH) [T] b6				
Subject: Time sensitive: Making your AC	ΓIV Participa	tion Public		

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

Francis S. Collins, MD, PhD NIH Director From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]

**Sent**: 5/16/2020 2:42:20 PM

To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Allen-Gifford, Patrice

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]; Pollock, Rachel (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]; Burklow, John (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]

Subject: Re: Time sensitive: Making your ACTIV Participation Public

I removed four people who have since responded both from the list and the email addresses. The remaining 14 non-responders are listed below.

From: Myles, Renate (NIH/OD) [E]	b6		
<b>Sent:</b> Friday, May 15, 2020 3:48 PM			
To: Collins, Francis (NIH/OD) [E]	b6		
Cc: Parker, Ashley (NIH/OD) [E]	DO	; Allen-Gifford, Patrice (NIH/OD) [E] <b>b6</b>	
<b>b6</b> ; Pollock, Rachel (NIF	I/OD) [E]	<b>b6</b> ; Burklow, John (NIH/OD) [E]	
b6	i		

Subject: FW: Time sensitive: Making your ACTIV Participation Public

Hi Francis:

The below individuals have not yet responded. Do you want to send out another email to them? There are 18 individuals. You'll need to delete the names below and cut and paste their emails in the bcc. Let me know if you'd like me to do it for you. They'd probably pay more attention if it came from you though. Your original email is at the bottom of this string.

Thanks, Renate



## Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

b6

## Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration

<b>b6</b>
Jay Grobler, Ph.D.
Director, Infectious Disease Biology
Merck & Co., Inc.
<b>b6</b>
David Payne, Ph.D.
Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline
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Frank Stegmeier, Ph.D.
Chief Scientific Officer
KSQ Therapeutics
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<u> </u>
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Senior Vice President, Global Development
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<b>b6</b>
Lionel Bascles, Ph.D.
Lionel Bascles, Ph.D. Senior Vice President, Global Head of Clinical Sciences & Operations
Lionel Bascles, Ph.D. Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi
Senior Vice President, Global Head of Clinical Sciences & Operations
Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi  b6
Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi    Carlos Garner, Ph.D.
Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi   b6  Carlos Garner, Ph.D.  Vice President, Global Regulatory Affairs
Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi   b6  Carlos Garner, Ph.D.  Vice President, Global Regulatory Affairs Eli Lilly and Company
Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi   b6  Carlos Garner, Ph.D.  Vice President, Global Regulatory Affairs
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Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi   b6  Carlos Garner, Ph.D. Vice President, Global Regulatory Affairs Eli Lilly and Company  b6  Peter Stein, M.D. Director of Office of New Drugs
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Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi    b6     Carlos Garner, Ph.D.     Vice President, Global Regulatory Affairs     Eli Lilly and Company     b6     Peter Stein, M.D.     Director of Office of New Drugs     Center for Drug Evaluation and Research     U.S. Food and Drug Administration     b6     Emilio Emini, Ph.D.     Director, TB & HIV Program     Bill & Melinda Gates Foundation     b6
Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi    b6     Carlos Garner, Ph.D.     Vice President, Global Regulatory Affairs     Eli Lilly and Company     b6     Peter Stein, M.D.     Director of Office of New Drugs     Center for Drug Evaluation and Research     U.S. Food and Drug Administration     b6     Emilio Emini, Ph.D.     Director, TB & HIV Program     Bill & Melinda Gates Foundation     b6     Kathrin Jansen, Ph.D.
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Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi    b6

Antonio Lanzavecchia, M.D.  Senior Vice President and Senior Research Fellow Vir Biotechnology, Inc.  Director, Institute for Research in Biomedicine, Bellin  b6	nzona, Switzerland		
Nancy Messonnier, M.D.  Director, Center for the National Center for Immuniz Centers for Disease Control and Prevention  b6	zation and Respiratory Diseases		
From: Collins, Francis (NIH/OD) [E] 6 Sent: Thursday, May 14, 2020 11:00 AM			
To: Collins, Francis (NIH/OD) [E] Cc: Myles, Renate (NIH/OD) [E] (FNIH) [T]  b6  Subject: Time sensitive: Making your ACTIV Participal	Meltzer, Abbey (FNIH) [T]	b6	>; Wholley, David

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NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

Francis S. Collins, MD, PhD NIH Director

From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]			
Sent:	5/16/2020 8:32:27 PM			
To:	Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group			
10.	(FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes			
	b6 LaVange, Lisa M b6 ; Sandeep Menon			
	b6 ; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange			
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham];			
	Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER)			
	[/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B.			
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John			
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price			
	b6			
	b6 Fron, Joe			
	<b>b6</b> ; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna			
	[/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; <b>b6</b>			
CC:	Demarcus b6 ; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative			
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan			
	[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]			
	[/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]			
Subject:	ACTIV TX-Clinical Master Protocol Outpatient mAbs Writing Team Meeting #1			
Attachments:	a5401-d02-051620_hold.docx			
Location:	b6			
	i			
Start:	5/18/2020 5:00:00 PM			
End:	5/18/2020 6:00:00 PM			
Show Time As:	Tentative			
Required	Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah			
Attendees:	(NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price;			
	b6			
r	Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna;			
	b6			
Optional	Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]			
Attendees:				

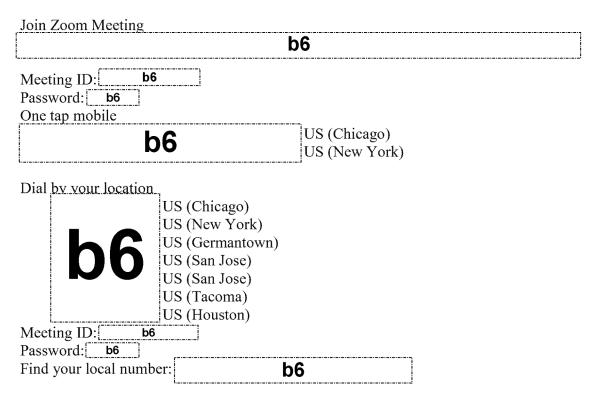
Dear ACTIV-2 Master Protocol Writing Team,

Thank you all for being willing to get together so quickly. I look forward to the ACTIV and the ACTG teams working together to make this protocol great and get it going quickly.

We will work to get a full list of participants and their roles together for this meeting to distribute. In the meantime, the ACTG team has been kind enough to send the current draft of their protocol for us to start from. They have noted to me that they have removed some agent specific information for confidentiality purposes, but all else should be ready for this group to review and start thinking and commenting on.

Thanks,

Stacey



From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	· · · · · · · · · · · · · · · · · · ·
Sent: To:	Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes    b6
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price
	b6
CC:	b6 Eron, Joe  b6 Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; b6  Demarcus b6 Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Attachments:	ACTIV TX-Clinical Master Protocol Outpatient mAbs Writing Team Meeting #1 a5401-d02-051620_hold.docx
Thank you al	7-2 Master Protocol Writing Team, all for being willing to get together so quickly. I look forward to the ACTIV and the ACTG teams other to make this protocol great and get it going quickly.
meantime, th from. They l	to get a full list of participants and their roles together for this meeting to distribute. In the e ACTG team has been kind enough to send the current draft of their protocol for us to start have noted to me that they have removed some agent specific information for confidentiality tall else should be ready for this group to review and start thinking and commenting on.
Thanks,	
Stacey	
Stacey J. Ad Director, Can Research Part Direct:	cer
Join Zoom M	lecting
	b6

Meeting ID:	b6 j	
Password: <b>b6</b>		
One tap mobile		
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Dial by your location	on_	
	US (Chicago)	
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h C	US (Germantown)	
<b>b6</b>	US (San Jose)	
	US (San Jose)	
	US (Tacoma)	
	US (Houston)	
Meeting ID:	o6	
Password: <b>b6</b>		
Find your local num	her k	<b>16</b>

From:		/O=EXCHANGELABS/OU= RECIPIENTS/CN=DCD875			4]	
Sent:	5/16/2020 8:37:37 PM					
To:	Bozzette, Sam (NIH/NCA)	ΓS) [E] [/o=ExchangeLabs/	ou=Exchange Admi	nistrative Group		
	(FYDIBOHF23SPDLT)/cn=	Recipients/cn=85f05a361	9cf47c7ae39d7bcf0	aac88d-bozzettesaa];	Butterton, Joan	
	[/o=ExchangeLabs/ou=Ex	change Administrative Gr	oup			
		Recipients/cn=219ecac4fa		e2490c3-joan_butter];	Collins, Sylva	
	(FDA/CDER) [/o=Exchang	eLabs/ou=Exchange Adm	nistrative Group			
	(FYDIBOHF23SPDLT)/cn=	Recipients/cn=f6b8f5880	57140fe988f0832c2	387725-Sylva.Colli]; Ju	ıdy Currier	
		change Administrative Gr				
	(FYDIBOHF23SPDLT)/cn=	Recipients/cn=890082c7c	1e34902b0f535320	cd16650-jscurrier.m];	De Claro, R. Angelo	
	(FDA/CDER) [/o=Exchang	eLabs/ou=Exchange Adm	nistrative Group			
		Recipients/cn=c495c3ee2	5ca461ba6a829b12	4062448-DECLAROR.f	d]; Mark Eisner	
	b6	; Keith Gottesdiener	b6	Eric Hughes		
	b6	; LaVange, Lisa M	b6	; Elliott Levy	<b>b6</b> ; Sandeep	
	Menon be		Peppercorn	b6	; Proschan, Michael	
		angeLabs/ou=Exchange A				
		Recipients/cn=7b4505920		dfbbb3e4-proscham];	Read, Sarah (NIH/NIAID)	
		=Exchange Administrative				
		Recipients/cn=527b16003				
	b6				ge Administrative Group	
		Recipients/cn=a583eced8		20bee21-priced.fda];	Rubin, Daniel B.	
		eLabs/ou=Exchange Adm	·			
		Recipients/cn=35c289105		.9042aad-RUBIND.fda	; Shen, Yuan Li	
		eLabs/ou=Exchange Adm				
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER)					
		change Administrative Gr				
				caa09bc-FARLEYJ.fdaJ	Goff, David (NIH/NHLBI)	
		=Exchange Administrative	·	100.40 (01.7.1)		
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	b6	; Wung, Peter /US	,	; Karen Lynn Pri		
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CC:	Mary Biggs <b>b6</b>	; Demarcus	b6	Macone, Erin	b6	
	Tountas, Karen (FNIH) [T]	[/o=ExchangeLabs/ou=Ex	kchange Administra	tive Group		
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan					
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Subject:	Note about ACTIV TX-Clir	nical Master Protocol Sub	group Meeting #19			

Dear ACTIV TX-Clinical Master Protocol Subgroup,

Similarly to my last note, many of you will see this meeting disappear from your calendar as well. We will be repurposing this for another discussion with the SARS-CoV-2 neutralizing mAbs subteam.

Thank you for your understanding and we look forward to updating you all on our progress on Thursday and Friday.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

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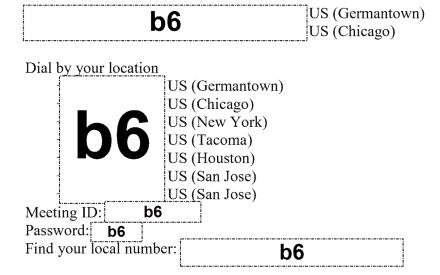
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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]			
Sent:	5/16/2020 8:42:31 PM			
То:	Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan			
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier			
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes    b6			
	b6  ; LaVange, Lisa M b6 ; Read, Sarah (NIH/NIAID) [E]			
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	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet			
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CC:	Demarcus b6 ; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative			
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan			
	[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]			
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Subject:	ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review			
Location:	b6			
	i			
Start:	5/20/2020 5:00:00 PM			
End:	5/20/2020 6:00:00 PM			
Show Time As:	Tentative			
Required	Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E];			
Attendees:	Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O			
Optional	Garner Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]			
Attendees:	bemarcus, Touricas, Karen (1 Min) [1], Wachter, Johathan, Enzabeth Kim, Farker, Asiney (Min) Ob) [2]			
Dear ACTIV	TX-Clinical Master Protocol mAbs Steering Committee,			
	our meeting today, this will be the call for us to review the Synopsis of the SARS-CoV-2			
neutralizing	mAb outpatient master protocol.			
Thanks,				
G.				
Stacey				
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Subject:	Follow-up to ACTIV TX-Cl	•			<b>-</b>	
Attachments:	ACTIV_Therapeutics-Clini				pdf	
				,	111	

Dear ACTIV TX-Clinical Master Protocol Subgroup,

Please find attached the action items and summary notes for yesterday's meeting. Please let us know if you have any additions or amendments.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

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Sent: To:	5/16/2020 11:58:56 PM  Marks, Peter			
CC:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]			
Subject:	RE: ChAdOx1			
vaccine W	f word of concern – let's be sure we don't come down too strong on b4 role in the recent G discussions, which expressed a perspective that probably needed to be heard. We don't want to b4 in a position that might lead to their decision to pull out of ACTIV. Better to draw them in ely.			
From: Mark	cs Peter d b6			
	day, May 16, 2020 3:13 PM			
	Anthony (NIH/NIAID) [E] b6 Mascola, John (NIH/VRC) [E] b6			
	ncis (NIH/OD) [E] <b>b6</b> Lane, Cliff (NIH/NIAID) [E] <b>b6</b>			
	y, David (FNIH) [T] b6 Tabak, Lawrence (NIH/OD) [E] b6 ; Parker,			
Ashley (NIH				
Subject: RE:	, , , , , , , , , , , , , , , , , , ,			
Subject. RE.	. CIPAGNI			
Dear Tony,				
Will certain	ly include you next week on this call.			
Best Regard Peter	ds,			
From: Fauci	i, Anthony (NIH/NIAID) [E] <b>b6</b>			
Sent: Thurse	day, May 14, 2020 9:12 AM			
To: Marks, F				
be				
	y, David N (NIH) <b>b6</b> ; Tabak, Lawrence A (NIH) <b>b6</b> ; Parker, Ashley S			
(NIH)	b6			
Subject: RE	: ChAdOx1			
I would a	also like to be on that call with the b4 CEO if we could possible arrange it.			
Anthony S. Director	. Fauci, MD			

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
31 Center Drive, MSC 2520
National Institutes of Health

please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of the NIAID by one of its representatives.  From: Marks, Peter b6 Sent: Thursday, May 14, 2020 9:05 AM	lt or
<b>Sent:</b> Thursday, May 14, 2020 9:05 AM	Þ.
To: Mascola, John (NIH/VRC) [E] b6 ;; Collins, Francis (NIH/OD) [E] b6 ; Lane,	
Cliff (NIH/NIAID) [E] b6  Cc: Fauci Anthony (NIH/NIAID) [E] b6 > Wholley David (ENIH) [T] b6 Tabak	
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Lawrence (NIH/OD) [E] <b>b6</b> Parker, Ashley (NIH/OD) [E <b>b6</b> Subject: RE: ChAdOx1	
Dear John,  Thanks for bringing the b4 issue up. I think that a call with their head of development and possibly also their CEO	
may be needed, and I wonder if Francis would like to join?	
Best Regards, Peter	
From: Mascola, John (NIH/VRC) [E] <b>b6</b> Sent: Thursday, May 14, 2020 9:03 AM  To: Marks, Peter <b>b6</b> ; Collins, Francis S (NIH) <b>b6</b> >; Lane, Henry C (NIH)	
To: Marks, Peter   b6  Collins, Francis S (NIH)   collins, Fra	
Cc: Fauci, Anthony S (NIH) 4 b6 Wholley, David N (NIH) 4 b6 Tabak, Lawrence A	
(NIH) b6 Parker, Ashley S (NIH) b6	
Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both a general agreement, with some useful recommendations on efficient ways to conduct phase 3.	and
One issues is that b4	]
D4	
<b>b4</b> When we asked for suggestions for DSMB, Kathrin said she d	id
not agree that we should ask for nominations – because this issue required more discussion – b4	
b4 Doug Lowy was on the call, so may be useful to get his perspective.	
John	
From: Marks, Peter b6 Sent: Thursday, May 14, 2020 6:23 AW	
To: Collins, Francis (NIH/OD) [E b6 >; Mascola, John (NIH/VRC) [E] b6 >; Lane,	

Cliff (NIH/NIAID) [E]	b6				
Cc: Fauci, Anthony (NIH,	/NIAID) [E]	b6	; Wholley, David (FNIH) [T]	b6	Tabak,
Lawrence (NIH/OD) [E]	b6		Parker, Ashley (NIH/OD) [E]	b6	>
Subject: RE: ChAdOx1					

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Among other things, Tony, John and I discussed the concept that in addition to harmonized protocols we would consider merging the first two vaccines that are currently aiming to start phase 3 into one master protocol if they appeared to be staying on schedule for a July 1 start. Planning on one DSMB for at least these two candidates therefore makes a lot of sense.

Later today I will be speaking with John again about this merged concept. After giving it very careful consideration, though it certainly involves significant extra work in protocol development and logistic planning, I believe that we should be actively planning for the two contingencies simultaneously:

- 1) Moderna and Oxford AZ enter phase 3 at different times (more than 2 weeks apart), in which case we will go with harmonized protocols, non-overlapping sites, and a single DSMB, and
- 2) Moderna and Oxford AZ enter phase 3 simultaneously (less than 2 weeks apart), in which case we should plan on one master protocol making use of all available sites. There is much to recommend this option, such that it is worth the effort in planning even if circumstances preclude proceeding along this path: 1) it could reduce the overall size of the trials by 10,000; 2) could help drive enrollment since fewer people will receive placebo; and 3) it will produce comparative efficacy data.

			D4		;
b4	that will have	to be addresse	ed, but these do not appear t	o be showsto	ppers. Happy to discuss
urther.					
Best Regards,					
Peter					
From: Collins, Fra	ncis (NIH/OD) [E]	b6			
	1ay 14, 2020 5:38	·			
<b>Γο:</b> Mascola, John	ı R (NIH) <	b6	; Lane, Henry C (NIH)	b6	; Marks, Peter
b6			i		
Cc: Fauci, Anthon	y S (NIH) <afauci@< td=""><td>niaid.nih.gov</td><td>&gt;; Wholley, David N (NIH) &lt;<u>d</u></td><td>vholley@fnih</td><td>org&gt;; Tabak, Lawrence A</td></afauci@<>	niaid.nih.gov	>; Wholley, David N (NIH) < <u>d</u>	vholley@fnih	org>; Tabak, Lawrence A
NIH) < lawrence.t	abak@nih.gov>; I	Parker, Ashley	S (NIH) <ashley.parker@nih.s< td=""><td>(OV&gt;</td><td></td></ashley.parker@nih.s<>	(OV>	

#### Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Thanks, Francis

Sent:	5/17/2020 1:30:43 PM
To:	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC:	Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD)
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	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Myles, Renate (NIH/OD)
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	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Buchbinder,
	Susan b6 Corey, Larry b6 Davis, Mark b6
	Emini, Emilio b6 Hanon, Emmanuel [emmanuel.hanon@gsk.com]; Haynes, Barton
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	b6 ; Jansen, Kathrin b6 Lanzavecchia, Antonio b6 ; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	Paul [/o=ExchangeLabs/ou=Exchange Administrative Group
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	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f34e73d1185b4c5383df3b73c87aa455-Nancy.santo]; Schuitemaker,
	Hanneke <b>b6</b> ; Tartaglia, Jim [ b6   Tolman, Brett [btolman@deloitte.com];
	Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bascles, Lionel
	<b>b6</b> Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry
	b6 Desrosiers , Betsy b6 Dickens, Jim (NIH/NCATS) [C]
	[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI)
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	<b>b6</b> ; Kurilla, Mike <b>b6</b> ; Nayak, Seema (NIH/NIAID) [E]
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Dear ACTIV Working Group Members,

Please see the comprehensive news clips on ACTIV provided by the NIH Office of Communications and Public Liaison.

## Comprehensive News Clips of the ACTIV Public-Private Partnership

NIH Launches Effort To Speed Up Development Of COVID-19 Treatments

## **NPR**

April 17, 2020 By Mary Louise Kelly

Heard on All Things Considered

In an bid to help speed up the development of potential treatment options and a vaccine for COVID-19, the National Institutes of Health on Friday announced a new public-private research partnership.

The new initiative will be spearheaded by the NIH but also include the Food and Drug Administration, other parts of the federal government and a list of 16 companies that includes some of the biggest players in the pharmaceutical industry. Among the companies participating in the effort are Pfizer, Johnson & Johnson and Merck.

"We need to have all hands on deck from every sector to speed up the process of identifying those treatments that are going to work and to get the vaccines also developed, tested, to make sure they're safe and effective in the maximum possible speed," said Dr. Francis Collins, director of the NIH, in an interview with NPR's *All Things Considered*.

The announcement comes after President Trump and public health officials on Thursday unveiled new <u>quidelines for states to begin reopening the country</u>. Health experts say that in order to safely do that, there needs to be more testing, contact tracing and better drugs to treat COVID-19. Ultimately, for things to truly return to normal, an effective vaccine is needed.

Collins said there are already two vaccines in phase one trials, and behind that, a series of more than 40 other vaccines being developed as well. But he cautioned that the public should expect failures along the way.

"Somewhere in there may be a winner, even if most of them are losers," he said.

Collins also provided an update on testing of antiviral drug, remdesivir, and shared his thoughts on Dr. Anthony Fauci, the high-profile director of the National Institute of Allergy and Infectious Diseases.

Here are excerpts from the conversation.

#### There's a lot of buzz about an antiviral called remdesivir.

Remdesivir is certainly, I think, at the top of most people's hopeful list, but not yet proven. Just to report, yesterday although not yet peer reviewed, that in a monkey model it looked as if this did provide benefit for COVID-19. ... We're running a human trial with now 800 participants enrolled more quickly than expected. We will know, I think, in the next two to four weeks whether it worked or not.

# [A] question about one of the most prominent faces of U.S. anti-virus efforts, Dr. Anthony Fauci ... Have you come under any pressure to fire him?

Absolutely not. He is a wonderful public servant, an amazingly smart infectious disease expert. He and I have a nightly phone call every evening to catch up on what's happened with his life down at the White House and mine trying to manage the NIH. He's the best ally I could ever have.

Listen to the full interview on All Things Considered at the audio link above.

# Drug Industry Coordinates Covid-19 Response With NIH

## **Bloomberg Law**

April 17, 2020 By Jeannie Baumann

- AbbVie, Eli Lilly, Merck among more than dozen drug companies involved
- Aims to coordinate biomedical research response globally

More than a dozen drug companies including Pfizer Inc., Johnson & Johnson, and Sanofi are coordinating their Covid-19 efforts with the NIH to push out new treatments and vaccines.

The public-private partnership plans to develop an international framework for prioritizing vaccine and drug candidates, streamlining clinical trials, coordinating regulatory processes across different countries, and using assets available among all collaborators to respond rapidly to both the current and future pandemics. The National Institutes of Health announced the Accelerating COVID-19 Therapeutic Interventions and Vaccines partnership Friday.

More than 300 clinical trials on Covid-19 are underway, and that number increases almost daily, a spokesperson for the Pharmaceutical Research and Manufacturers of America told Bloomberg Law earlier this week. But more than 90% of drug candidates fail in the clinical trial stage, and there are concerns about manufacturers' ability to scale up production to treat a worldwide pandemic once a vaccine or therapeutic becomes available.

NIH Director Francis S. Collins said the partnership aims to break down traditional boundaries in the biomedical research ecosystem to identify and prioritize the most promising therapies for clinical trials.

"Because we all know this particular virus is going to be with us for some time, the best hope we have as we think to limit the number of ill people and deaths from this disease is to develop and test rigorously therapeutic interventions that may save lives," Collins said Friday at a press briefing.

#### **Clinical Trials**

There are already about 100 ideas that have been put forward for clinical therapeutics, Collins said. He said that by June or July he expects to have some data showing which of the promising compounds to treat Covid-19 are working and should be prioritized in drug development.

There are also more than 40 vaccine candidates that are now in clinical trials, Collins said.

Esther Krofah, executive director at FasterCures, said Friday at a separate policy event hosted by the Commonwealth Fund that there are about 86 active vaccine projects and that she expects two dozen more to enter clinical trials by the end of the summer or early fall. Faster Cures, which is part of the think tank the Milken Institute, is <u>tracking</u> the development of potential Covid-19 medicines and vaccines.

The Food and Drug Administration has been "very open to creative ideas," about rapidly moving forward with a vaccine once it's proven safe and effective, Collins said.

Flexibility in how scientists set up their clinical trials and using real-world evidence can help speed up the process, Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, said at the Commonwealth Fund event.

"We can't dismiss out of hand any potential useful design here—real-world evidence base, traditional base, or otherwise," Marks said.

Marks didn't rule out the possibility of issuing an emergency authorization for a vaccine, but he said it would depend on the evidence and if the virus is still circulating at that point.

#### Collaboration Needed

The NIH is leading the partnership with the nonprofit Foundation for the NIH, the Health and Human Services Office of the Assistant Secretary for Preparedness and Response, the Centers for Disease Control and Prevention, the FDA, and the European Medicines Agency.

The chief scientific officers of Pfizer and Johnson & Johnson both said in statements that ending the pandemic is beyond the ability of any single entity.

"COVID-19 is the most significant global health challenge of our lifetime, and it will take all of us working together as a global community to put an end to this pandemic," Paul Stoffels, chief scientific officer at Johnson & Johnson, said.

Other companies involved in the effort are AbbVie Inc., Amgen Inc., AstraZeneca plc, Bristol Myers Squibb, Evotec, GlaxoSmithKline plc, KSQ Therapeutics Inc., Eli Lilly and Co., Merck & Co. Inc., Roche Holding AG, Takeda Pharmaceutical Co. Ltd., and Vir Biotechnology.

Gilead, whose antiviral product remdesivir has been described as the most advanced stage of development, wasn't among the companies listed in the NIH announcement.

#### **Future Implications**

The work of the partnership could boost the ability of drug companies and the NIH to respond to future pandemics, Collins said.

ACTIV's work could serve as a roadmap for public-private partnerships to identify and prioritize experimental compounds and to develop more creative approaches to creating new tools and standards for evaluating medical products.

"I don't think anybody involved in this standing back and looking at it would say this is really just a one-shot deal, even though we're focused on it right now for the urgency of the moment," Collins said.

-With assistance from Jacquie Lee

To tame testing chaos, NIH and firms join forces to streamline coronavirus vaccine and drug efforts

#### Science

April 17, 2020 By Jocelyn Kaiser More than 100 treatments and vaccines are in development to stem the COVID-19 pandemic, and some onlookers have worried that this sprawling and potentially duplicative effort is <u>wasting time and resources</u>. Hoping to bring order to the chaos, the National Institutes of Health (NIH) and major drug companies today <u>announced</u> a plan to stage carefully designed clinical trials of the drugs and vaccines they have decided are the highest priorities for testing and development.

The public-private partnership involves NIH, other U.S. government agencies, 16 pharma companies and biotechs, and the nonprofit Foundation for the National Institutes of Health (FNIH). It aims to develop "an international strategy" for COVID-19 research, a press release states. However, NIH Director Francis Collins told reporters during a press call today that, "It is primarily a U.S. focused effort."

The initiative, called Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), aims to make efficient use of NIH funding and its clinical trial networks by working with companies to evaluate data on early candidates, selecting those that have the most promise and are not already part of rigorous human tests.

NIH is stepping in partly because of concerns that some potential treatments, such as <a href="https://www.hydroxychloroquine">hydroxychloroquine</a>/chloroquine, are being touted by some researchers as effective based on poorly designed trials. "We need the best research standards," says former NIH director and Sanofi executive Elias Zerhouni, who sits on FNIH's board. "To me, the whole effort is to create a synergy between all of the players."

Collins said NIH began discussions with companies just 1 month ago, and plans gelled at a 3 April meeting. There was "unanimous agreement that the time has come to put aside any of the obstacles ... [to] such a public-private partnership and bring all the full resources and ideas together in a variety of ways that neither sector could do alone," Collins said.

## Joining forces

ACTIV is partly modeled on a long-established FNIH-organized program called the Accelerating Medicines Partnership, in which companies join forces with NIH to generate shared data, such as biomarkers in Alzheimer's disease. Its goals include giving companies access to animal models and drug screening programs in high-security biosafety labs, as well as developing a "master protocol" and setting clinical standards for assessing a drug's efficacy that would be shared across trials. Companies will also share data on immune responses to candidate vaccines. Although focused on the United States, NIH says ACTIV is also working with the European Medicines Agency.

NIH is assembling working groups of scientists who will inventory drugs and vaccines at different stages of development, and then decide which are most promising for future testing and not already in well-designed studies. In making that list, the experts will also consider which untested compounds can most quickly move into human trials, and which could be manufactured in large quantities. The top-rated compounds will get priority for the \$1.8 billion Congress gave NIH for COVID-19 research as part of pandemic recovery bills, and preferred access to NIH's dozen or more clinical trial networks.

Collins noted that once ACTIV has started coordinating clinical trials, it might become easier to rapidly start, end, or redesign trials to focus on the most promising candidates. As an example, he noted that NIH easily recruited 800 patients, 300 more than needed, to test the drug remdesivir (results are expected soon). If an additional candidate compound was available, he noted, NIH could have offered those 300 patients the option of becoming involved in a different trial instead.

NIH and its partners say they have put off, for now, deciding how to answer potentially thorny questions about intellectual property (IP) ownership and the pricing of any new treatments developed under the partnership. That's a reasonable strategy given the urgency, says science policy specialist Robert Cook-Deegan of Arizona State University, Tempe. "It's pretty clear that they're aware the IP could get complicated," he says. And he doubts that pricing issues "will play out the way it usually does, with companies pricing to maximize and government passively going along," if only because there is likely to be intense public scrutiny of the effort.

Collins pointed out that companies are unlikely to be motivated by profits after seeing their own clinical trial efforts shut down by COVID-19. Executives are "desperate" to get their businesses running again and "therefore willing to do whatever it takes both altruistically and practically," he predicted.

#### Growing efforts to coordinate

The NIH project joins numerous other COVID-19 research coordination efforts around the world. In the United Kingdom, for example, a trial testing several drugs called RECOVERY is being led by the University of Oxford and tapping nearly 1000 patients at 132 hospitals run by the country's National Health Service. Although the U.S. effort has been slower than some others to get started, "no doubt when the NIH gets going, it will be a ... very efficient study," says Mene Pangalos, executive vice president of bioPharmaceuticals R&D at AstraZeneca. "Hopefully, they won't do the same molecules they

are doing in the U.K., and between us all, we'll learn faster." NIH says its working groups include representatives from efforts such as RECOVERY to avoid such duplication.

One global health leader is noticeably absent from the list of ACTIV's partners: the World Health Organization (WHO). It, too, has been coordinating COVID-19 research, organizing a set of global drug trials called **SOLIDARITY**.

WHO chief scientist Soumya Swaminathan said her agency welcomes the NIH effort. But for vaccines, she contends that WHO is well-positioned to coordinate the field with an expert group that's now being formed. "The best and most efficient way would be to consider one large global study which would look at different vaccine candidates," she says.

Collins says NIH is keeping tabs on WHO's efforts as it makes its own plan. And infectious disease expert Daniel Bausch of the London School of Hygiene & Tropical Medicine says WHO does not have the capacity to launch the effort NIH has in mind. "It will be important, however, to have NIH and WHO coordination, especially to ensure equitable participation in the conduct of the trials and access to the products that they might produce," Bausch says.

Richard Danzig, former secretary of the U.S. Navy who is heavily involved in international vaccine planning, says that while "the NIH effort is commendable," it doesn't directly take on another challenge once a vaccine has been developed: how to make enough to vaccinate the world's population. "We need also," Danzig says, "to prepare global manufacturing for vaccine production."

With reporting by Jon Cohen and David Malakoff.

## U.S., European health agencies to partner drugmakers in coronavirus fight

#### Reuters

April 17, 2020 By Saumya Sibi Joseph

U.S. health agencies, the European drug regulator and 16 top drugmakers will collaborate on vaccine and drug development efforts to fight the coronavirus pandemic, the U.S. National Institutes of Health said on Friday.

The partnership, known as the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), will focus on coordinating regulatory decisions and provide funding to move promising therapies into human trials.

"We need to bring the full power of the biomedical research enterprise to bear on this crisis," NIH Director Dr. Francis Collins said in a statement bit.ly/34HYTfk.

The participants include the U.S. Food and Drug Administration, the European Medicines Agency and drugmakers Pfizer Inc, Johnson & Johnson and GlaxoSmithKline Plc.

There are currently no approved treatments or vaccines for the coronavirus, which has infected 2.14 million globally, according to a Reuters tally.

There are over 100 potential vaccine and therapeutic candidates for COVID-19, the respiratory illness caused by the novel coronavirus, and the partnership aims to help prioritize development and connect clinical trial networks to test new and repurposed candidates quickly and efficiently.

#### Azar announces new effort to streamline COVID-19 research

#### **NBC News**

April 17, 2020 By Sara G. Miller

The National Institutes of Health is launching a public-private partnership aimed at developing a national strategy to coordinate COVID-19 drug and vaccine research.

Research for coronavirus therapies and vaccines across the country has been scattered and disconnected, in a number of unrelated clinical trials. The new initiative, called "Accelerating COVID-19 Therapeutic Interventions and Vaccines," or ACTIV, aims to coordinate and streamline these efforts.

"The ACTIV partnership will bring new levels of coordination and speed to public and private work on therapies and vaccines for COVID-19," HHS Sec. Alex Azar said in a statement Friday. "By bringing together 16 pharmaceutical

companies and five government agencies here and abroad, the ACTIV partnership will accelerate the amazing work being done every day by scientists and innovators inside and outside of government."

The government agencies include HHS's Biomedical Advanced Research and Development Authority, the Centers for Disease Control and Prevention, the Food and Drug Administration, and abroad, the European Medicines Agency.

NIH partners with 16 drug companies in hopes of accelerating Covid-19 treatments and vaccines

## **STAT**

April 17, 2020 By Lev Facher

The National Institutes of Health on Friday announced it would launch a sweeping public-private partnership between federal researchers and 16 pharmaceutical companies, aimed at coordinating and accelerating the development of Covid-19 treatments and vaccines.

The partnership, to be known as Accelerating Covid-19 Therapeutic Interventions and Vaccines, or ACTIV, is meant to standardize research between the federally funded researchers and a broad array of drug companies, and prioritize research into drugs and vaccines that are having high near-term potential.

"Now is the time to come together with unassailable objectivity to swiftly advance the development of the most promising vaccine and therapeutic candidates that can help end the COVID-19 global pandemic," Francis Collins, the NIH director, said in a statement.

The new collaboration will focus on standardizing the methods and models that researchers are using to test promising Covid-19 compounds. It will also provide researchers access to high-level laboratory facilities and standardize endpoints to ensure different companies and researchers are judging potential medicines by the same criteria. Finally, it would establish one joint control arm to be shared among all clinical trials, the NIH said in a press release.

The partnership will establish a system to precisely coordinate clinical trials to make sure all trials have adequate capacity and can tailor their populations to "different populations and disease stages."

It will also create a steering committee to effectively determine which drugs should be prioritized for further research and which drugs should be deprioritized — effectively, to cull the group of over 100 potential treatments and vaccines, keeping only the most promising.

The announcement comes as drug companies and government researchers around the world scramble to develop cures and vaccines to fight the Covid-19 pandemic, which has killed roughly 145,000 people worldwide and 33,000 in the U.S. alone.

NIH, the federal government's roughly \$39 biomedical research agency, has already played a prominent role. Tony Fauci, who leads the National Institute of Allergy and Infectious Diseases — an institute within NIH — has emerged as a key adviser within the Trump administration's coronavirus response.

The National Heart, Lung, and Blood Institute, another institute within NIH, last week launched research projects measuring the efficacy of hydroxychloroquine, the antimalarial drug that President Trump has touted as a promising coronavirus treatment. Last week, NIAID and a trio of other institutes announced a separate study aimed at measuring the true rate of coronavirus infection in the U.S. by measuring the number of adults who have coronavirus antibodies but have not displayed symptoms.

Trump made his first visit to the NIH's campus last month.

HHS launches public-private partnership to develop vaccines, therapies to treat coronavirus

#### **FOX News**

April 17, 2020 By Brooke Singman

The Department of Health and Human Services on Friday announced plans to launch a new public-private partnership to develop a national strategy to create vaccines and therapies to treat the novel coronavirus.

On Friday, the National Institutes of Health and the Foundation for NIH announced the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership.

More than a dozen biopharmaceutical companies, HHS's Biomedical Advanced Research and Development Authority, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration and the European Medicines Agency will partner to develop a strategy for a coordinated research response to the COVID-19 pandemic.

"The ACTIVE partnership will bring new levels of coordination and speed to public and private work on therapies and vaccines for COVID-19—work that NIH, HHS, and the Trump administration began literally days after the coronavirus threat was identified in China in January," HHS Secretary Alex Azar said in a statement Friday.

"To save lives and bring life back to normal in the United States and around the world, we need COVID-19 vaccines and therapies on the market as soon as possible," he continued, adding that the ACTIV partnership "will accelerate the amazing work being done every day by scientists and innovators inside and outside of government."

He added that the National Institute of Health has "an extensive track record of coordinating these development efforts for new biological threats, and they are well-suited to lead this part of the whole-of-government, whole-of-America response President Trump has marshaled to defeat COVID-19."

The announcement of the public-private partnership comes after President Trump unveiled a set of guidelines titled "Opening up America Again" and declared that the U.S. was moving on to its next stage in the fight against the coronavirus.

Trump announced a bipartisan council of lawmakers dedicated to restarting the economy,

The Trump administration's guidelines outline what individuals, businesses, health care workers and more should do over three phases in reopening the economy, with states only making it to the first phase if they see a decrease in the number of cases within their borders over 14 days.

The guidelines, which pass the decision on when to move to each phase to governors and local officials, are a reversal for Trump on comments made earlier this week that indicated he wanted to be the one deciding when the stay-at-home orders and business closures would lift.

New York Gov. Andrew Cuomo said this week, though, that the crisis will not be over until there is a vaccine, which officials say could take 12 to 18 months to happen.

"That's when it's over," he said.

Chaotic search for coronavirus treatments undermines efforts, experts say

Federal officials say they are devising plans for a wide-ranging partnership to organize research

# **Washington Post**

April 15, 2020 By Carolyn Johnson

In a desperate bid to find treatments for people sickened by the coronavirus, doctors and drug companies have launched more than 100 human experiments in the United States, investigating experimental drugs, a decades-old malaria medicine and cutting-edge therapies that have worked for other conditions such as HIV and rheumatoid arthritis.

Development of effective treatments for covid-19, the disease the virus causes, would be one of the most significant milestones in returning the United States to normalcy. But the massive effort is disorganized and scattershot, harming its prospects for success, according to multiple researchers and health experts. Researchers working around-the-clock describe a lack of a centralized national strategy, overlapping efforts, an array of small-scale trials that will not lead to definitive answers and no standards for how to prioritize efforts, what data to collect or how to share it to get to answers faster.

"It's a cacophony — it's not an orchestra. There's no conductor," said Derek Angus, chair of the department of critical care medicine at University of Pittsburgh School of Medicine, who is leading a covid-19 trial that will test multiple therapies. "My heart aches over the complete chaos in the response."

The global biomedical research establishment could be one of most powerful assets in the campaign against the new virus, with experts all over the world — and especially the scientific and medical powerhouse of the United States — in rare alignment in their focus on a single enemy. Some large trials designed to be definitive have launched. But with more than 500 human clinical trials worldwide, the lack of coordination puts the world at risk of ending up with a raft of inconclusive and conflicting studies and little idea of what interventions work for the next wave of illness.

Francis Collins, director of the National Institutes of Health, the nation's largest biomedical research agency, acknowledged researchers' frustrations but said in an interview Wednesday he has been working behind the scenes to launch an unprecedented public-private partnership to address the problems. He said the framework involves top pharmaceutical companies such as Pfizer and Johnson & Johnson, domestic and international government agencies including the European Medicines Agency, and academic research centers.

Collins said the month-long discussions have been kept under wraps to ensure buy-in for an approach likely to require sacrifices of personal recognition, scientific credit and profit — a centralized decision, for example, not to proceed with tests of one company's drug in order to move faster on a competitor's.

"I think we have the necessary clout to steer this whole complicated ecosystem," he said. "When you look at some of the things that are happening sporadically, we may be unlikely to learn what we need to from such disconnected, small trials. The whole point is to replace that with a coherent, evidence-based approach. ... I want to know what works, and I want to have it answered by June or July."

Agency officials said further details would be released in coming days.

Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases (NIAID), said in an email Tuesday that the partnership led by Collins is the "functional equivalent of a National Strategy."

While Collins was working on developing that strategy, hospitals, drug companies, government labs and individual doctors were flooding the system with proposals for drugs and other interventions to test against the virus — an outpouring that reveals how siloed and fragmented the research enterprise remains. For example, there are more than two dozen separate U.S. trials listed for the anti-malarial drug hydroxychloroquine, all with different designs. Some use the drug as a preventive, others as a treatment. Some use it alone, some with other drugs or vitamins, and some have no comparison group to tell if the drug was responsible for the outcome. That will make it more difficult to conclude whether, or in what circumstances, the drug may work.

Collins said a working group is addressing this problem by sifting through about 100 possible covid-19 treatments to decide which are the six to eight most promising drugs to move forward in large-scale trials. Those will be deployed in large clinical trial networks.

The new federal effort is motivated in part by what happened in China. Clifford Lane, deputy director for clinical research and special projects at NIAID, traveled to the origin of the outbreak in February as part of an international delegation to help the world learn from the Chinese experience. He was troubled by the lack of a strategic plan to prioritize and fast-track the most promising treatments, leading to a mosaic of inconclusive findings.

"We do have to have a bigger strategy than every university, every institute and — to be blunt — every country" working on their own research efforts, Lane said in an interview.

At the heart of the problem is the basic question of whether a drug really works. Typically, drugs and medical interventions are first tested in small clinical trials that establish safety before the most promising ones are funneled into bigger trials, in an iterative and years-long process. These trials, which typically randomly assign patients to receive either a drug or a placebo, prove that medicines, vaccines and medical procedures are effective and safe. But with the urgency of the coronavirus threat, timelines have been squeezed, doctors are doing uncontrolled experiments as they administer regular care, and the typical model for research is too slow.

# Prioritizing research

David Boulware, an infectious-disease physician and scientist at the University of Minnesota, has gotten at least 50 emails from companies and researchers with treatments they want to test. The urgency to find something — anything — for patients who have nothing other than supportive care has led researchers to pull everything off the shelf: a mix of existing drugs that show promise, stem cell treatments and brand new compounds designed specifically against covid-19.

The energy is remarkable, but it needs to be channeled. Clinical trials, whether for an HIV drug or a brand new medicine, compete for many of the same patients. If there are too many trials at a hospital, none of them may enroll enough patients

to get clear results. If there are too many similar small trials running in parallel, their results individually may be inconclusive and the data could have so many differences they may not be able to be pooled.

"There's all sorts of people wanting to try anything, because people are desperate," Boulware said.

He and others who were unaware of Collins's plans argue that national leadership — whether guidance on how to prioritize trials, a central body coordinating efforts, or a mechanism to play matchmaker among institutions working on similar ideas — could help channel the ubiquitous scientific desire to make a bigger, faster impact.

Some large-scale efforts are already underway: The World Health Organization has organized a massive trial in 90 countries of four promising therapies. The National Institutes of Health is conducting a test of the antiviral medication remdesivir at more than 50 institutions and last week launched a large trial for an anti-malarial medication. A \$50 million effort at the Duke Clinical Research Institute will test hydroxychloroquine in 15,000 health-care workers and create a registry that can be tapped to speed up future trials, such as for a vaccine.

"People should not be fatalistic that we're going to have a paucity of evidence for things that provide benefit," Collins said. "I hope we'll have three to four of those [treatments] by the summer."

But as the federal effort has proceeded largely in secret, individual institutions have scrambled to set up committees of experts who evaluate which trials make sense to move forward. At the University of Pennsylvania, a weeks-old committee gives priority scores to trials based on criteria such as whether they will compete with existing efforts and how they are to enroll all the patients needed to get a result. A task force at Duke University does a similar review.

"There's a lot of stuff bubbling up. It would seem like a sensible thing to do would be to align everyone around the same trials, not one trial for each context and not have each institution do its own thing and at the end of the day everyone has done a small trial ... and we don't know what to make of it," said Steven Joffe, a bioethicist at the University of Pennsylvania. "Let's get to an answer."

Many proposed trials overlap — using the same drug, such as the anti-malaria treatment hydroxychloroquine that has been touted by President Trump, his personal lawyer Rudolph W. Giuliani and conservative talk show host Laura Ingraham.

Boulware is halfway through one such hydroxychloroquine trial, which examines whether the drug is effective at preventing the disease or in treating people with mild cases. People who participate will receive either the drug or a vitamin in the mail.

He said he is motivated by his experience working on Ebola, when by the time a well-designed trial was up and running, the outbreak was dying down. He plowed ahead with his hydroxychloroquine trial weeks before he heard — last Friday — the National Institutes of Health had declined to fund it. He found international collaborators through chance and social media when some Canadian researchers emailed to ask if he would share his trial design with them. He ended up connecting the Canadians with each other and is now working on overcoming the complex legal requirements to share data.

But now, his trial is potentially competing with a bunch of others that also test hydroxychloroquine all across the country — and enrollment has slowed in recent days.

## Risks of inconclusive evidence in the social media age

Small trials and even anecdotal reports of treatments that appear to have worked on small groups of patients already are being shared, sowing both hope and confusion about the evidence.

A study published Friday in the New England Journal of Medicine reported on 53 people who took remdesivir, a failed Ebola drug Trump has praised and many families have tried to access outside of trials. The results were impossible to interpret, though, since some of those patients might have gotten better on their own and there was no comparison group of patients who did not receive the drug. Hydroxychloroquine, the cheap and readily available anti-malarial drug, also already has been widely used in patients despite only suggestive evidence it might work.

As more small-scale studies are designed, the risks of inconclusive but suggestive results multiply — and paradoxically, they could make it harder to conduct well-designed clinical trials that get to the bottom of whether a treatment works. Well-designed clinical trials require patients to be willing to be randomly assigned to receive the treatment — or a placebo.

Emma Meagher, chief clinical research officer at the University of Pennsylvania's Perelman School of Medicine, said her institution's study of the malaria drug in severely ill patients does not have a comparison group that receives a placebo

because the media around the drug has made it the standard of care despite the lack of evidence. Every meeting, she said, begins with a discussion about how to prevent the next experimental therapy from becoming like hydroxychloroquine.

In some ways, designing research studies when clinicians have an imperative to give their patients the best care possible is an inherently tricky situation. Outside of top-tier research hospitals, patients may not have access to trials, so clinicians may have little option but to give them drugs in what amounts to an uncontrolled experiment. The Infectious Diseases Society of America released guidelines last week recommending that clinicians should give experimental drugs only in trials, but safety-net and rural hospitals are less likely to have access to those.

"Do we really want to have [some] people trying new different things and the rest of you sit and wait?" asked Benjamin Linas, an infectious-disease physician working on oversight of clinical trial protocols at Boston Medical Center.

#### Lost time

Many researchers have said they are hopeful a national strategy will help unify and speed up the search but lament the time already lost. The United States did not have a pandemic clinical trials network ready to be activated, but existing clinical trials networks, such as those used to test HIV treatments, are now being repurposed. Collins said he had never seen research move faster, but in a pandemic that can still feel slow.

"We have imperfect networks. I mean, there are some there, but they've never been tested in this way," said Adrian Hernandez, vice dean for clinical research at Duke University School of Medicine. "Having a common infrastructure that can do rapid-cycle trials — that would be beneficial."

Collins said he began partnering with private companies, research institutions and other agencies in mid-March. Had he started sooner, he said, the urgency of the situation might not have been clear to those groups he had to convince to work together. He disagrees significant time has been lost and noted the efforts were able to piggyback on an existing framework for pursuing drugs with industry collaboration called the Accelerating Medicines Partnership.

Partnerships that previously took a year and a half to build were put together in a week, he said.

"I think it is a world record for anything of this sort. It might have been difficult to get full unanimous agreement to what is clearly unprecedented — for a willingness to give up control," Collins said.

As with other areas of pandemic planning, many hope the United States will learn from this lesson, that it needs a preparedness plan not only for allocating essential supplies and scaling up testing but also in plotting research.

"The problem is we need to remember to invest in preparedness, at times when we're not affected with a pandemic or epidemic," said Barbara Bierer, director of the regulatory foundations, ethics and the law program of the Harvard Clinical and Translational Science Center. "And it's hard to repurpose or commit resources to something that doesn't appear immediate on the horizon."

Thank you, Ashley

Ashley Parker, Ph.D.
Special Assistant to Acting Chief of Staff to the NIH Director
Office of the Director | National Institutes of Health
Tel: 301-594-7743



From:	Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]						
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Subject:	FW: ChAdOx1						
Flag:	Follow up						
	ve handle this? I think we agreed that calling b4 at this point would likely not be productive. If this cuss getting b4 vaccine on board, that is another matter. Thoughts?						
From: Marks,							
	y, May 16, 2020 3:13 PM						
	thony (NIH/NIAID) [E] b6 ; Mascola, John (NIH/VRC) [E] b6 ; Mascola, John (NIH/VRC) [E] b6						
•	is (NIH/OD) [E]						
Ashley (NIH/C							
Subject: RE: 0	\						
Dear Tony,							
Will certainly	include you next week on this call.						
Best Regards, Peter							
	Anthony (NIH/NIAID) [E] b6						
<b>To:</b> Marks, Pe	ay, May 14, 2020 9:12 AM eter b6 ; Mascola, John R (NIH) b6 ; Collins, Francis S (NIH)						
b6	Lane, Henry C (NIH) ( b6 )						
I	David N (NIH) 6 ; Tabak, Lawrence A (NIH) 66 ; Parker, Ashley S						
(NIH) Subject: RE: 0	b6 >						
I would als	o like to be on that call with the b4 CEO if we could possible arrange it.						
Anthony S. F	fauci, MD						
Director National Inst	itute of Allergy and Infectious Diseases						
Building 31,	ww						
31 Center Dr	ive, MSC 2520						
	itutes of Health						
Bethesda, M Phone: (	D 20892-2520 b6						
FAX: (301) 4							
E-mail:	<b>b6</b>						

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From: Marks, Peter <	b6			
<b>Sent:</b> Thursday, May 14, 2020 9				
To: Mascola, John (NIH/VRC) [E]	] b6	Collins, Francis (NIH/OD) [E]	b6	; Lane,
Cliff (NIH/NIAID) [E] b	- '			
Cc: Fauci, Anthony (NIH/NIAID)	[E] <u>b6</u>	Wholley, David (FNIH) [T]	b6	Tabak,
Lawrence (NIH/OD) [E]	b6	Parker, Ashley (NIH/OD) [E]	b6	
Subject: RE: ChAdOx1				-
Dear John,				
Thanks for bringing the <b>b4</b> is may be needed, and I wonder if		t a call with their head of development to join?	and possibly als	o their CEO
Best Regards, Peter				
From: Mascola, John (NIH/VRC)	[E] <b>b6</b>			
<b>Sent:</b> Thursday, May 14, 2020 9				
	6 Col	lins, Francis S (NIH) <b>b6</b>	; Lane, Henry	C (NIH)
b6		,		
Cc: Fauci, Anthony S (NIH) (NIH) b6 Subject: RE: ChAdOx1	; Parker, Ashley S	; Wholley, David N (NIH)	j; labak,	Lawrence A
presented the harmonized prot	ocol approach and	cine WG. Yesterday on the vaccine cling high level details of phase 3 design. The ations on efficient ways to conduct pha	ere was good in	• .
One issues is that		b4		
		b4		
b4		. When we asked for suggestions	for DSMB, Kath	rin said she did
		cause this issue required more discuss may be useful to get his perspective.		b4
John				
From: Marks, Peter	b6			
<b>Sent:</b> Thursday, May 14, 2020 6		Advantage of the second		
To: Collins, Francis (NIH/OD) [E]		Mascola, John (NIH/VRC) [E]	b6	; Lane,
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Cc: Fauci, Anthony (NIH/NIAID)		; Wholley, David (FNIH) [T]	b6	; Tabak,
Lawrence (NIH/OD) [E]	b6	, Parker, Ashley (NIH/OD) [E]	b6	j
Subject: RE: ChAdOx1				

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Among other things, Tony, John and I discussed the concept that in addition to harmonized protocols we would consider merging the first two vaccines that are currently aiming to start phase 3 into one master protocol if they appeared to be staying on schedule for a July 1 start. Planning on one DSMB for at least these two candidates therefore makes a lot of sense.

Later today I will be speaking with John again about this merged concept. After giving it very careful consideration, though it certainly involves significant extra work in protocol development and logistic planning, I believe that we should be actively planning for the two contingencies simultaneously:

- 1) Moderna and Oxford AZ enter phase 3 at different times (more than 2 weeks apart), in which case we will go with harmonized protocols, non-overlapping sites, and a single DSMB, and
- 2) Moderna and Oxford AZ enter phase 3 simultaneously (less than 2 weeks apart), in which case we should plan on one master protocol making use of all available sites. There is much to recommend this option, such that it is worth the effort in planning even if circumstances preclude proceeding along this path: 1) it could reduce the overall size of the trials by 10,000; 2) could help drive enrollment since fewer people will receive placebo; and 3) it will produce comparative efficacy data.

		b4		
b4 that will h	ave to be addı	essed, but these do not appear to	be showsto	opers. Happy to discuss
further.				
Best Regards,				
Peter				
From: Collins, Francis (NIH/OD)	[E]	b6		
<b>Sent:</b> Thursday, May 14, 2020 5	5:38 AM			
To: Mascola, John R (NIH)	b6	; Lane, Henry C (NIH)	b6	; Marks, Peter
b6 ♭				
Cc: Fauci, Anthony S (NIH)	b6	; Wholley, David N (NIH)	b6	Tabak, Lawrence A
(NIH) b6	; Parker, Ash	nley S (NIH) b6	<u> </u>	
Subject: ChAdOx1		<u> </u>		

#### Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? **b4,b5** agree in principle to a single DSMB?

Thanks, Francis

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***Updated with New Protocol Version***

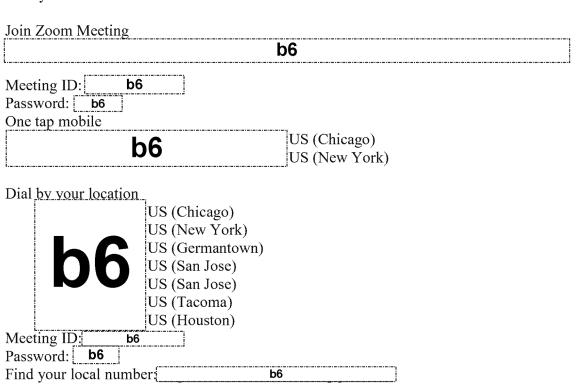
Dear ACTIV-2 Master Protocol Writing Team,

Thank you all for being willing to get together so quickly. I look forward to the ACTIV and the ACTG teams working together to make this protocol great and get it going quickly.

We will work to get a full list of participants and their roles together for this meeting to distribute. In the meantime, the ACTG team has been kind enough to send the current draft of their protocol for us to start from. They have noted to me that they have removed some agent specific information for confidentiality purposes, but all else should be ready for this group to review and start thinking and commenting on.

Thanks,

Stacey



From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price
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CC: Subject:	Eron, Joseph J Jr b6  Demarcus b6 Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  NEW PROTOCOL VERSION for ACTIV TX-Clinical Master Protocol Outpatient mAbs Writing Team Meeting #1
Attachments: Dear ACTIV	a5401-d03-activ-051620.docx  7-2 Master Protocol Writing Team,
Please find a	ttached a new protocol version from the ACTG team for discussion at tomorrow's meeting.
Thanks,	
Stacey	
Stacey J. Ad Director, Can Research Par Direct:	ncer necer necer necer necer necer necer necer necer necer neces neces neces neces neces neces neces neces neces
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From:	Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George
	(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura  b6  Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri
	b6 Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike b6 Wachtel, Jonathan [jwachtel@deloitte.com]; Weinmann, Gail (NIH/NHLBI) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]
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	[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John  b6 ; Criffield, Robin b6 ; Hamilton, Nancy
	b6 ; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth b6 ; Pico, Dianna
	(NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora
	<b>b6</b> Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana
	b6 ; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
	Heaton, Penny [

	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael						
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	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]						
Subject:	Summary and action items - CT Capacity WG meeting #8						
Attachments:	Clinical_Trial_Capacity_Working_Group_Meeting_9_Final.pdf						

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #9 (May 15, 2020) of the full working group. The next full working group meeting is scheduled for Tuesday, May 19 at 9 am eastern time USA.

Cheers! Karen

Karen H. Tountas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

b6 fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



Confidentiality Notice: Information contained in this e-mail and attachments may be legally privileged and confidential. If you are not an intended recipient, you are hereby notified that dissemination, distribution or copying this e-mail and attachments is strictly prohibited; please delete the e-mail and attachments immediately.

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR] Sent: 5/18/2020 1:37:20 PM To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc] Subject: RE: Time sensitive: Making your ACTIV Participation Public Thank you! From: Wooldridge, Shannon (NIH/OD) [E] Sent: Monday, May 18, 2020 9:17 AM To: Myles, Renate (NIH/OD) [E] Parker, Ashley (NIH/OD) [E] Pollock, b6 b6 Rachel (NIH/OD) [E] b6 Subject: RE: Time sensitive: Making your ACTIV Participation Public No replies from Baric, Deming, or Jansen in FC's inbox. I just ran a search. From: Myles, Renate (NIH/OD) [E] Sent: Monday, May 18, 2020 9:16 AM b6 >; Pollock, Rachel (NIH/OD) [E] To: Parker, Ashley (NIH/OD) [E] { Wooldridge, Shannon (NIH/OD) [E] b6 Subject: RE: Time sensitive: Making your ACTIV Participation Public Importance: High Hi Rachel and Shannon: Would you check FC's mailbox for this information ASAP? We need to launch the webpage this morning. Thanks, Renate From: Parker, Ashley (NIH/OD) [E] Sent: Monday, May 18, 2020 7:57 AM Pollock, Rachel (NIH/OD) [E] To: Myles, Renate (NIH/OD) [E] b6 Wooldridge, Shannon (NIH/OD) [E] Subject: Re: Time sensitive: Making your ACTIV Participation Public Hi Renate, Rachel, and Shannon, We've made lots of progress! Shannon — can we see if the 3 ACTIV participants responded to Dr. Collins privately over the weekend? Thank you, Ashley

/ 17, 2020, at 11:15 PM, Myles, Renate (NIH/OD) [E] <b>b6</b> wrote:
Hi Ashley and Rachel:
Below are the three people I did not hear from. I searched my inbox. Just wanted to double check that they didn't just respond to Francis. Thanks, Renate
Ralph Baric, Ph.D. William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health  66
Damon Deming, Ph.D. Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration  b6
Kathrin Jansen, Ph.D. Senior Vice President and Head of Vaccine Research and Development Pfizer  b6
From: Collins, Francis (NIH/OD) [E]   b6  Sent: Thursday, May 14, 2020 11:00 AM  To: Collins, Francis (NIH/OD) [E]   b6
Cc: Myles, Renate (NIH/OD) [E] b6 Meltzer, Abbey (FNIH) [T] b6 Wholley, David (FNIH) [T] b6
Subject: Time sensitive: Making your ACTIV Participation Public
Dear ACTIV Colleagues:
Yes, this message is for you, though your address was in the bcc line!
NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for

Francis

Francis S. Collins, MD, PhD NIH Director From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS] Sent: 5/18/2020 1:56:11 PM To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil] Subject: FW: YOUR INPUT NEEDED: ACTIV Webpage We will need to add the additions below to our leadership logo slide -- FYI From: Collins, Francis (NIH/OD) [E] b₆ Sent: Monday, May 18, 2020 9:54 AM To: Myles, Renate (NIH/OD) [E] Parker, Ashley (NIH/OD) [E] b6 Wolinetz, Carrie (NIH/OD) [E] Cc: Burklow, John (NIH/OD) [E] & b6 Brodd, Lauren (NIH/OD) [E] b6 Subject: RE: YOUR INPUT NEEDED: ACTIV Webpage OK to add those leadership groups. But I'm troubled about removing Jansen – she's the co-chair of the Vaccines WG. Let me bug her one more time. FC From: Myles, Renate (NIH/OD) [E] b6 Sent: Monday, May 18, 2020 9:35 AM To: Collins, Francis (NIH/OD) [E] b6 ; Parker, Ashley (NIH/OD) [E] Cc: Burklow, John (NIH/OD) [E] ; Wolinetz, Carrie (NIH/OD) [E] Brodd, Lauren (NIH/OD) [E] € Subject: YOUR INPUT NEEDED: ACTIV Webpage Importance: High Hi Francis and Ashley: We plan to push the ACTIV website live at around 10:00 a.m. ET this morning. A few things: FNIH indicated that Karuna Therapeutics, RTI, and Fred Hutchinson should be listed as part of the Leadership Organizations, but that they defer to NIH. Please let me know if I should add these organizations to the list of Leadership Organizations?

We did not hear from the below individuals, so we plan to remove them from the website until we hear from them. I also understand there are several more individuals joining the working groups, so we'll likely have a second round of addtions.

### Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

**b6** 

Damon Deming, Ph.D.
Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration
b6
Kathrin Jansen, Ph.D.
Senior Vice President and Head of Vaccine Research and Development
Pfizer
b6
Beth Bell, M.D., MPH
Clinical Professor, Global Health
University of Washington
Thanks,

Renate

From: Sent: To: Subject:	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]  5/18/2020 1:58:33 PM  Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]							
Thanks!!								
	dridge, Shannon (NIH/OD) [	[E] {	b6					
<b>Sent:</b> Monda <b>To:</b> Myles R	ay, May 18, 2020 9:17 AM lenate (NIH/OD) [E]	b6	Parker, Ashley (NIH/OD) [E]	h6	Pollock,			
Rachel (NIH)	/OD) [E] <b>b6</b>							
<b>Subject:</b> RE:	Time sensitive: Making you	ır ACTIV Partio	cipation Public					
No replies fr	rom Baric, Deming, or Janse	n in FC's inbo	x. I just ran a search.					
From: Myles	s, Renate (NIH/OD) [E]	b6						
<b>Sent:</b> Monda	ay, May 18, 2020 9:16 AM		; Pollock, Rachel (NIH/OD) [E]					
To: Parker, A	Ashley (NIH/OD) [E]	b6	; Pollock, Rachel (NIH/OD) [E] [	b6				
Wooldridge, Subject: RE:	, Shannon (NIH/OD) [E] { Time sensitive: Making you	b6	ination Public					
Importance:		n ACTIVITATION	ipation rubile					
•	3							
Hi Rachel an	nd Shannon:							
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Would you d	check FC's mailbox for this i	nformation AS	SAP? We need to launch the webpag	ge this morning.				
Thanks,								
Renate								
	r, Ashley (NIH/OD) [E]	b6						
Sent: Monda	ay, May 18, 2020 7:57 AM				<del>-</del>			
<b>To:</b> Myles, R Wooldridge	lenate (NIH/OD) [E]	b6	}; Pollock, Rachel (NIH/OD) [E]	b6				
woolariage, <b>Suhiect:</b> Re:	, Snannon (NIH/OD) [E] [ Time sensitive: Making you	ır ACTIV Partio	ination Public					
Judject. No.	Time sensitive. Making you	ar Activitation	sipation i done					
Hi Renate, R	tachel, and Shannon,							
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the weeken		— can we see	e il the 3 ACTIV participants respond	ed to Dr. Comins p	orivately over			
Thank you,								
Ashley								
On May 17,	2020, at 11:15 PM, Myles, F	Renate (NIH/C	DD) [E] <b>b6</b> wrote	e:				
			Ci					
Hi A	shley and Rachel:							

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Ralph Baric, Ph.D.										
Villiam R. Kenan, Jr., Distinguished Professor, Department of Epidemiology rofessor, Department of Microbiology and Immunology										
								University of North Carolina, Gillings School of Global Public Health  66		
Damon Deming, Ph.D.	Damon Deming Ph.D.									
irologist, Division of Antiviral Products, Office of New Drugs										
U.S. Food and Drug Administration										
b6										
Kathrin Jansen, Ph.D. Senior Vice President and Head of Vac Pfizer  b6	ccine Research	n and Development								
From: Collins, Francis (NIH/OD) [E]	b6									
<b>Sent:</b> Thursday, May 14, 2020 11:00 A	.M	·· <del>····</del> ··								
Sent: Thursday, May 14, 2020 11:00 A  To: Collins, Francis (NIH/OD) [E]	b6	BASSAF -								
Cc: Myles, Renate (NIH/OD) [E]	b6	; Meltzer, Abbey (FNIH) [T]	b6							
Wholley, David (FNIH) [T] ∮ b6	3									

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

Subject: Time sensitive: Making your ACTIV Participation Public

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

Francis S. Collins, MD, PhD NIH Director

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP] Sent: 5/18/2020 2:11:04 PM To: Baric, Ralph /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; b6 j; Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas b6 Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar CIV USARMY MEDCOM USAMRIID (USA) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group CC: (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy Hughes, Eric **b6** Jansen, Kathrin ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, ; Rose Li [rose.li@roseliassociates.com]; Dana Carluccio Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];

Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
	(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D  b6
	b6 ; Dave Frankowski b6 } Baric, Toni C b6 } Baric, Toni C Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [bstratton@DELOITTE.com]
Subject:	ACTIV Preclinical working group (Tuesday meeting)
Location:	b6
Start:	4/22/2020 2:00:00 PM
End:	4/22/2020 3:00:00 PM
Show Time As:	• •
Recurrence:	Weekly
Required	every Wednesday from 10:00 AM to 11:00 AM
Attendees:	h6
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	b6 Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
	b6 Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E];
Outional	Tomas Cihlar; b6 SARMY MEDCOM b6 (USA)
Optional Attendees:	Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine
Attendees:	(NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T];
	James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi
	Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha
	(NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D;
	Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood;
	Stratton, Benjamin
Changing time	e for preclinical WG
Joseph Menet	tski is inviting you to a scheduled Zoom meeting.
Join Zoom Me	
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Maritim ID C	
Meeting ID: Password:	
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US (Tacoma)
US (Houston)

Meeting ID: b6

Password: b6

Find your local number: b6

From:	om: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]							
Sent:	5/18/2020 2:12:39 PM							
To:	Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Parker, Ashley (NIH/OD) [E]							
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		ative Group 6b2244466140faa95aaaafe06ebd70-parkera	acl					
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CC: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group								
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Subject:	RE: YOUR INPUT NEEDED: ACTIV Webpage							
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mar 5 mic to								
From: Myles,	Renate (NIH/OD) [E] <b>b6</b>							
Sent: Monday	y, May 18, 2020 10:11 AM							
To: Collins, Fr	ancis (NIH/OD) [E]	Parker, Ashley (NIH/OD) [E] ; Wolinetz, Carrie (NIH/OD) [E]	b6					
	John (NIH/OD) [E] < <b>b6</b>	Wolinetz Carrie (NIH/OD) [F]	b6					
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	( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( )							
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I looked up bo	oth RTI and Fred Hutch and they are bot	h non-profits, so perhaps we can just lis:	t them as non-profits.					
Eroma Collins	Francis (NUL/OD) [E]	····1						
	, Francis (NIH/OD) [E] <b>66</b>	l						
-	y, May 18, 2020 10:07 AM							
To: Myles, Re	nate (NIH/OD) [E]	Parker, Ashley (NIH/OD) [E]	b6					
Cc: Burklow, J	nate (NIH/OD) [E] <b>b6</b> John (NIH/OD) [E]	, Wolinetz, Carrie (NIH/OD) [E]	<b>b6</b> ;					
	n (NIH/OD) [E]   <b>b6</b>							
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I think you co	ould expand the Non-profit category	$^\prime$ to Non-profit/Academic, and that w	ould capture RTI and the					
Hutch.								
F	D							
•	Renate (NIH/OD) [E] <b>b6</b>	. <u></u>						
Sent: Monday	y, May 18, 2020 10:03 AM							
To: Collins, Fr	ancis (NIH/OD) [E] LC	; Parker, Ashley (NIH/OD) [E]	b6					
	John (NIH/OD) [E] <b>b6</b>	>; Wolinetz, Carrie (NIH/OD) [E]	b6					
	n (NIH/OD) [E] <b>b6</b>							
	OUR INPUT NEEDED: ACTIV Webpage							
Subject. NE. 1	TOOK INPOT NEEDED. ACTIV Webpage							
		ve are Government, Industry, and Non-F						
Industry, but	what about RTI and Fred Hutchinson Ca	ncer Center? Do we need to add an Aca	demic category?					
From: Collins	, Francis (NIH/OD) [E] <b>b</b> 6	·····						
•	y, May 18, 2020 9:54 AM		h.C.					
-	nate (NIH/OD) [E] <b>b6</b>	; Parker, Ashley (NIH/OD) [E]	b6					
Cc: Burklow, J	John (NIH/OD) [E]	; Wolinetz, Carrie (NIH/OD) [E]	b6					

Brodd, Lauren (NIH/OD) [E] <b>b6</b> Subject: RE: YOUR INPUT NEEDED: ACTIV Webpage
OK to add those leadership groups.
But I'm troubled about removing Jansen – she's the co-chair of the Vaccines WG. Let me bug her one more time.
FC
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We plan to push the ACTIV website live at around 10:00 a.m. ET this morning. A few things:
FNIH indicated <b>that Karuna Therapeutics, RTI, and Fred Hutchinson</b> should be listed as part of the Leadership Organizations, but that they defer to NIH. Please let me know if I should add these organizations to the list of Leadership Organizations?
We did not hear from the below individuals, so we plan to remove them from the website until we hear from them. I also understand there are several more individuals joining the working groups, so we'll likely have a second round of addtions.
Ralph Baric, Ph.D. William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health
Damon Deming, Ph.D. Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration  b6
Kathrin Jansen, Ph.D. Senior Vice President and Head of Vaccine Research and Development Pfizer
Beth Bell, M.D., MPH Clinical Professor, Global Health University of Washington
Thanks, Renate

Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS] Sent: 5/18/2020 2:21:33 PM To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil] Subject: RE: YOUR INPUT NEEDED: ACTIV Webpage Let's wait and follow what Renate post on the website today. I was only referring to the 3 – not everything below. From: George, Jill (NIH/OD) [E] b6 Sent: Monday, May 18, 2020 10:17 AM To: Parker, Ashley (NIH/OD) [E] b6 Subject: RE: YOUR INPUT NEEDED: ACTIV Webpage Hi Ashley, Please confirm my thoughts in RED caps. No rush. Thanks! From: Parker, Ashley (NIH/OD) [E] b6 Sent: Monday, May 18, 2020 9:56 AM To: George, Jill (NIH/OD) [E] Subject: FW: YOUR INPUT NEEDED: ACTIV Webpage We will need to add the additions below to our leadership logo slide -- FYI b6 From: Collins, Francis (NIH/OD) [E] Sent: Monday, May 18, 2020 9:54 AM Parker, Ashley (NIH/OD) [E] b6 To: Myles, Renate (NIH/OD) [E] b6 Cc: Burklow, John (NIH/OD) [E] Wolinetz, Carrie (NIH/OD) [E] b6 Brodd, Lauren (NIH/OD) [E] Subject: RE: YOUR INPUT NEEDED: ACTIV Webpage OK to add those leadership groups. But I'm troubled about removing Jansen – she's the co-chair of the Vaccines WG. Let me bug her one more time. FC b6 From: Myles, Renate (NIH/OD) [E] Sent: Monday, May 18, 2020 9:35 AM b6 To: Collins, Francis (NIH/OD) [E] Parker, Ashley (NIH/OD) [E] **b6** Cc: Burklow, John (NIH/OD) [E] { Wolinetz, Carrie (NIH/OD) [E] b6 Brodd, Lauren (NIH/OD) [E] b6 Subject: YOUR INPUT NEEDED: ACTIV Webpage Importance: High Hi Francis and Ashley:

We plan to push the ACTIV website live at around 10:00 a.m. ET this morning. A few things:

APAR0000013131

FNIH indicated that Karuna Therapeutics NO CHANGE, RTI NO CHANGE, and Fred Hutchinson NO CHANGE should be listed as part of the Leadership Organizations, but that they defer to NIH. Please let me know if I should add these organizations to the list of Leadership Organizations?

We did not hear from the below individuals, so we plan to remove them from the website until we hear from them. I also understand there are several more individuals joining the working groups, so we'll likely have a second round of addtions.

Ralph Baric, Ph.D. ARE WE ADDING A NEW CATEGORY CALLED <u>ACADEMIC LEADERS</u> WITH TWO LOGOS? William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health  b6
Damon Deming, Ph.D. NO CHANGE
Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration
b6
Kathrin Jansen, Ph.D. NO CHANGE UNLESS WE HEAR OTHERWISE Senior Vice President and Head of Vaccine Research and Development Pfizer
b6
Beth Bell, M.D., MPH (LOGO 2 UNDER ACADEMIA LEADERS) Clinical Professor, Global Health University of Washington
Thanks, Renate

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP] Sent: 5/18/2020 2:26:39 PM b6 Tomas Cihlar To: b6 Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm] CC: Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy **b6**; Hughes, Eric **b6**; Jansen, Kathrin ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes b6 ]; Diamond, Michael

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Subject:		al working group (Fr				
Attachments:			, <del></del>	jpm.xlsx; Therape	eutic information reque	st form-v8.docx;
	2020-05-15_Preclin	nical_WG_Summary	_d4.docx			

[Confidential and Pre-decisional]

Dear Preclinical working group members and invitees,

Thank you for a very interesting meeting on Friday. Please find the attached minutes for your review. Also, I am attaching the current therapeutic information request and the animal model inventory. Finally I have pasted the action items below.

Best regards, Joe

# **Action Items:**

- Dr. Jay Rappaport will share a white paper to ACTIV leadership outlining the necessary responsibilities of an NPRC coordinating group.
- Joe will share the newest version of the therapy request form to the WG after making the changes discussed. [with this email]
- Joe will send members the most recent WG animal model inventory. [with this email]
- Dr. Srinivas Rao will lead the WG in developing IP protection strategies by generating a first draft of the topics that need to be addressed.
- Dr. Rappaport will share guidelines on how the NPRCs enable academic researchers to publish data derived from research that uses IP.

Origina	l Appointmen	t					
From: Men	etski, Joseph	(FNIH) [T]					
Sent: Tueso	day, April 14, 2	2020 6:48 PM					
То:	b6	; Tomas Cihlar;	b6	Menetski, Joseph (FNIH) [T];			
	<b>b6</b>						
		b6		; Parker, Ashley (NIH/OD) [E]; Collins,	Francis		
(NIH/OD) [	E];	b6	Adams, Peter (C	OS/ASPR/BARDA); Rao, Srinivas /US; Andersoi	n, James		
(NIH/OD) [	E]; Qashu, Feli	icia (NIH/OD) [E]	<del>-</del>				
Cc: Nancy I	Haigwood; Lov	wy, Douglas (NIH/NCI) [I	E]; Simon, Dina (N	IIH/OD) [C]; Wholley, David (FNIH) [T]; Austir	١,		

Christopher (NIH/NCA Eric; Jansen, Kathrin; K (FNIH) [T]; Santos, Mic	Kurilla, Michael (NIH chael (FNIH) [T]; Ada	/NCATS) [E]; Lowy, D im, Stacey (FNIH) [T];	ouglas (NCI); Read, James, Stephanie (I	Sarah (NIH/NIAID) [ FNIH) [T]; Alvarez, R	E]; Tountas, Karer osa Maria; Kim,
Elizabeth; Tolman, Bre	•	•	·	·	. • .
Enrique (NIH/NCATS)   Rodriguez, Robin D; D;					; Hild, Sheri
(NIH/OD) [E]	ave Flankowski, Floi	rence, clint (Min/MA	iiD) [E], [		j mila, snen
Subject: ACTIV Preclin	nical working group (	Friday meeting)			
When: Friday, May 15			Fastern Time (IIS & (	Canada)	
Where:	, 2020 II.00 AW IZ	<b>b6</b>	Lastern Time (05 &	canadaj.	
i					
Holding time					
Joseph Menetski is inv	viting you to a sched	uled Zoom meeting.			
Join Zoom Meeting	b6			1	
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Meeting ID: <b>b6</b> Password: <b>b6</b> One tap mobile					
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Meeting ID: <b>b6</b>					
Password: b6					
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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]

**Sent**: 5/18/2020 2:29:24 PM

To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]

Subject: RE: NOW REALLY URGENT, need your response: Making your ACTIV Participation Public

Yes.

From: Myles, Renate (NIH/OD) [E]	b6	
Sent: Monday, May 18, 2020 10:27 AW	1	
To: Collins, Francis (NIH/OD) [E]	b6	
Subject: RE: NOW REALLY URGENT, ne	ed your respo	onse: Making your ACTIV Participation Public
Should we just include her? I need to p	ush the webs	site live.
From: Collins, Francis (NIH/OD) [E]	b6	
Sent: Monday, May 18, 2020 9:58 AM		
To: b6		
10.		
Cc: Myles, Renate (NIH/OD) [E]	b6	

Hi Kathrin,

Sorry to keep bugging you, and it's possible we missed seeing your earlier response, but is it OK to list you on the ACTIV web site? As co-chair of the Vaccines WG, it would be very unfortunate to omit you – and yet we wanted to get permission before doing so. We want to post this imminently today.

Thanks, Francis

From: Collins, Francis (NIH/OD) [E]	b6			
<b>Sent:</b> Saturday, May 16, 2020 6:02 PM				
To: Collins, Francis (NIH/OD) [E]	b6	<del>-</del> -]		
Cc: Myles, Renate (NIH/OD) [E]	DO	Meltzer, Abbey (FNIH) [T]	b6	; Wholley, David
(FNIH) [T] <b>b6</b>		··		
Subject: URGENT, need your response: N	Making vour A	CTIV Participation Public		

Dear ACTIV Colleagues:

Yes, this follow up and increasingly urgent message is for you, even though your address was in the bcc line! We have heard from almost all of the ACTIV Working Group participants, and so far all have been happy to have their names listed in the ACTIV web site. But we still haven't heard from YOU.

Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please don't delay further, and send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 5 p.m. ET tomorrow, Sunday May 17.

Thanks, Francis Francis S. Collins, MD, PhD NIH Director

From:	Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]						
Sent:	5/18/2020 3:46:05 PM						
To:	Jansen, Kathrin <b>b6</b>						
CC:	Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group						
Subject:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr] RE: NOW REALLY URGENT, need your response: Making your ACTIV Participation Public						
Flag:	Follow up						
Thanks!							
<b>To:</b> Collins, Fr <b>Cc:</b> Myles, Re	, Kathrin & b6 y, May 18, 2020 11:01 AM rancis (NIH/OD) [E] b6 nate (NIH/OD) [E] < COMPANY NOW REALLY URGENT, need your response: Making your ACTIV Participation Public						
Dear Francis,	I missed my deadline, thanks for the prompt. Ok to use my name as a co-chair. Best Kathrin						
Sent: Monda To: Jansen, Ka Cc: Myles, Re	, Francis (NIH/OD) [E] <b>b6</b> y, May 18, 2020 9:58 AM athrin <b>b6</b> nate (NIH/OD) [E] <b>b6</b> ERNAL] NOW REALLY URGENT, need your response: Making your ACTIV Participation Public						
Hi Kathrin,							
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Thanks, Fran	ncis						
Sent: Saturda To: Collins, Fr	, Francis (NIH/OD) [E]						
(FNIH) [T]	b6  ENT, need your response: Making your ACTIV Participation Public						
Dear ACTIV C	olleagues:						
	w up and increasingly urgent message is for you, even though your address was in the bcc line! We have lmost all of the ACTIV Working Group participants, and so far all have been happy to have their names						

listed in the ACTIV web site. But we still haven't heard from YOU.

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Thanks, Francis

Francis S. Collins, MD, PhD NIH Director

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR] 5/18/2020 7:21:29 PM Sent: Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; ; Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell **b6** Greg Glenn ; Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; b6 Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; **b6** (USA) **b6** ; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56fdbe4598a57b423d484dcf9f-offit.email]; | Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccba4e3caaf5eb5d3586b1cc-Jonathan.Se]; b6 ; Tal Zaks Tolman, Brett [btolman@deloitte.com];[ ; Hopps, Markay CC: Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; ; Jeneffer Haynes b6 Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; ; Isabel Ramsey b6 Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  $(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cc\underline{e098457896b2df19fa172c87}-ccolvis]; Desrosiers, Betsylonder (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cc\underline{e098457896b2df19fa172c87}-ccolvis]; Desroy (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cc\underline{e098457896b2df19fa172c87}-ccolvis]; Desroy (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cc\underline{e098457896b2df19fa172c87}-ccolvis]; Desroy (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cc\underline{e09845766}-ccolvis]; Desroy (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cc\underline{e09845766}-ccolvis]; Desroy (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cc\underline{e09845766}-ccolvis]; Desroy (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cc\underline{e09845766}-ccolvis]; Desroy (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cc\underline{e09845766}-ccolvis]; Desroy (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cc\underline{e09845766}-ccolvis]; Desroy (FYDIBOHF25C0C)/cn=Recipients/cn=4b7e84cc\underline{e0984566}-ccolvis]; Desroy (FYDIBOHF265C0C)/cn=Recipients/cn=4b7e84ccalvis$ ; Hughes, Eric **b6** ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John

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	b6 ; Paul Gillard b6 ; Hamilton, Holli (OS/ASPR/BARDA)
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamil]; Modjarrad, Kayvon CIV
	USARMY <b>b6</b> (USA) <b>b6</b> , Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som];
	Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R.
	(CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina
	[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
	Wachtel, Jonathan [jwachtel@DELOITTE.com]; Stratton, Benjamin [bstratton@DELOITTE.com]; Anderson, Margaret
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	b6 ; Bethany Stokes
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End:	5/28/2020 7:00:00 PM
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Required	b6 Lowy, Douglas (NIH/NCI) [E]; b6 Arvin, Ann; Beth Bell
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Attendees:	bo // bo leavaier/ Walles, E
	b6 Greg Glenn; b6 ; Haynes,
	<b>b6</b>   Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
	Messonnier, Nancy (CDC/DDID/NCIRD/OD); b6 JARMY b6 (USA); Offit, Paul;
	b6 Seals, Jonathan (OS/ASPR/BARDA); b6 Tal Zaks
Optional	Tolman, Brett; b6 Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
Attendees:	(NIH/NCI) [E]; b6 Jeneffer Haynes; b6
, , , , , , , , , , , , , , , , , , , ,	b6 ; Austin, Sarah (NIH/NIAID) [E]; b6 ; Isabel Ramsey; Parker,
	Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Wholley, David (FNIH) [T];
	Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James,
	Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS)
	[E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV
	USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R.
	(CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton,
	Benjamin; Anderson, Margaret; b6 Bethany Stokes
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Do not deli	ete or change any of the following text
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You can also	o dial 173.243.2.68 and enter your meeting number.
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Sent:	5/18/2020 7:21:31 PM Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group							
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CC:		[btolman@delo	- :	b6	Hopps, Mark	· :	b6	
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Tolman, Brett [btolman@deloitte.com]; i; Hopps, Markay CC: Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Jeneffer Haynes b6 Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; ; Isabel Ramsey b6; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John

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	Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group								
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	Wachtel, Jonathan [jwachtel@DELOITTE.com]; Stratton, Benjamin [bstratton@DELOITTE.com]; Anderson, Margaret								
	[marganderson@deloitte.com]; b6 Bethany Stokes								
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	Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James,								
	Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS)								
	[E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); b6								
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From:	Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]							
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	Jonathan [jwachte	el@DELOITTE.co	om]; Stratton, I	Benjamin [bst	ratton@DELOI	TTE.com]; An	derson, Marg	aret
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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR] 5/18/2020 7:22:01 PM Sent: Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; h; Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell Cavaleri Marco b6 Greg Glenn Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc] b6 ; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56fdbe4598a57b423d484dcf9f-offit.email]; Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccba4e3caaf5eb5d3586b1cc-Jonathan.Se]; ; Tal Zaks CC: b6 Tolman, Brett [btolman@deloitte.com]; Hopps, Markay Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; ի; Jeneffer Haynes Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange . [[Administrative Group (FYDIBOHF23SPDLT)/cn=Recipiénts/cn=292fcb760f9f4f199ebe343e08ef1781-austins Isabel Ramsey ; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy ; Hughes, Eric b6 Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR] 5/18/2020 7:22:02 PM Sent: To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Kathrin.Jansen@pfizer.com; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell ይ Cavaleri Marco b6 ; Greg Glenn Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc];harks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56fdbe4598a57b423d484dcf9f-offit.email]; Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccba4e3caaf5eb5d3586b1cc-Jonathan.Se]; Tal Zaks Tolman, Brett [btolman@deloitte.com]; CC: ; Hopps, Markay b6 Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; ; Jeneffer Haynes [ **b6** Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Isabel Ramsey ; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf7957/e2aa8d1-jamesstj; Colvis, Christine (NIH/NCATS)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
	b6 ; Hughes, Eric b6 ; Kurilla, Michael (NIH/NCATS) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John  b6 ]; Paul Gillard b6 Hamilton, Holli (OS/ASPR/BARDA)
	b6 ]; Paul Gillard b6 Hamilton, Holli (OS/ASPR/BARDA)
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	( · · · · · · · · · · · · · · · · · · ·
	USARMY MEDCOM WRAIR (USA) b6 Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som];
	Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R.
	(CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie
	(CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina
	[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
	Wachtel, Jonathan [jwachtel@DELOITTE.com]; Stratton, Benjamin [bstratton@DELOITTE.com]; Anderson, Margaret
	[marganderson@deloitte.com]; b6 ; Bethany Stokes
	b6 ; Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]
Subject:	Canceled: ACTIV Vaccines Working Group meeting
Location:	b6
Start:	6/9/2020 4:00:00 AM
End:	6/10/2020 4:00:00 AM
Show Time As:	
Show Time As.	nee
Required	b6 ; Lowy, Douglas (NIH/NCI) [E]; b6 Arvin, Ann; Beth Bell
Attendees:	b6 Cavaleri Marco; b6
	b6 ; Haynes,
	b6 ; Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
	Messonnier, Nancy (CDC/DDID/NCIRD/OD); <b>b6</b> CIV USARMY MEDCOM WRAIR (USA); Offit, Paul;
	b6 Seals, Jonathan (OS/ASPR/BARDA); b6 Tal Zaks
Optional	Tolman, Brett; <b>b6</b> ; Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
Attendees:	(NIH/NCI) [E]; b6 ; Jeneffer Haynes; b6
	b6 Austin, Sarah (NIH/NIAID) [E]; b6 ; Isabel Ramsey; Parker,
	Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E];
	Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T];
	Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E];
	Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul
	Gillard; Hamilton, Holli (OS/ASPR/BARDA); b6 CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil;
	Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie
	(CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret;
	b6 Bethany Stokes; Ann Arvin

From:	Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP	
C 4 -	FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]	
Sent:	5/18/2020 8:31:14 PM	
То:	Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group	. 1
	FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD	)
	E] <b>b6</b> Dolsten, Mikael <b>b6</b> ; Fauci, Anthony (NIH/NIAID) [E]	
	b6 ; Gibbons, Gary (NIH/NHLBI) [E] b6 ; Pao, William	
	b6 ; Stoffels, Paul b6 ]; Tabak, Lawrence (NIH/OD) [E]	
	b6 Parker, Ashley (NIH/OD) [E] b6 Wholley, David (FNIH) [T]  b6 : Colvis, Christine (NIH/NCATS) [E] b6 : Desrosiers, Betsy	
	, , , , , , , , , , , , , , , , , , , ,	
į	b6 Hughes, Eric b6 ; Jansen, Kathrin	
	b6 Kurilla, Michael (NIH/NCATS) [E] b6 ; Lowy, Douglas (NCI)	
	b6 ; Read, Sarah (NIH/NIAID) [E] b6 Young, John b6 ;	
	reire, Maria (FNIH) [T] b6 ; Wolinetz, Carrie (NIH/OD) [E] b6 ; Austin,	
	Christopher (NIH/NCATS) [E] <u>b6</u> ; Anderson, James (NIH/OD) [E] <b>b6</b> ;	
	ane, Cliff (NIH/NIAID) [E] b6 ; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange	
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel];	
	Culp, Michelle (NIH/OD) [E] <u>b6</u> ]; Disbrow, Gary (OS/ASPR/BARDA) <u>b6</u> ;	
	Marks, Peter (FDA/CBER) ( b6 ; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchang	;e
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]	
CC:	Adam, Stacey (FNIH) [T] <b>b6</b> ; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret	
	marganderson@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [ningonzalez@deloitte.com];	
	ames, Stephanie (FNIH) [T] <u>b6</u> ; Kim, Elizabeth [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T]	
	<b>b6</b> ; Santos, Michael (FNIH) [T] <b>b6</b> ; Stratton, Ben [bstratton@deloitte.com];	
	olman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] <b>b6</b> ; Wachtel, Jonathan	
	jwachtel@deloitte.com]; Barasch, Kimberly (NIH/NIAID) [C] <b>b6</b> ; Conrad, Patricia	
	NIH/NIAID) [E] <b>b6</b> ; Dimishkov, Roxanne (NIH/NHLBI) [C] <b>b6</b> ;	
	McManus, Ayanna (NIH/OD) [E] <b>b6</b> Protasiewicz, Ann <b>b6</b> ;	
	homas, Ashley (FDA/CDER) [Ashley.Thomas@fda.hhs.gov]; Wood, Gretchen (NIH/OD) [E] <b>b6</b> ;	
	anellato, Ann <b>b6</b> ; Burrus-Shaw, Cyndi (NIH/OD) [E] <u>b6</u> ; Simon, Dina	
	NIH/OD) [C] <b>b6</b> ; Li, Rose <b>b6</b> ; FNIH Central Account	
	FNIH@roseliassociates.com]; Awwad, David (NIH/NIAID) [C] b6 ; Zottoli, Jessica	
	b6 ; Togashi, Mieko (NIH/NCI) [E] b6 ; Sepulveda, Dorina (FNIH)	f
	T] <b>b6</b> ; Hardesty, Rebecca (NIH/OD) [C] <b>b6</b> ; Lagos, Enrique	
	NIH/NCATS) [E] <b>b6</b> ; Carver, Trea (NIH) [C]; <b>b6</b> ; Lowy, Douglas (NIH/NCI) [E]	
	b6	
	:	
Subject:	ACTIV Executive Committee Teleconference	
Location:	b6	
	<u></u>	
Start:	5/20/2020 7:30:00 PM	
End:	5/20/2020 9:00:00 PM	
Show Time As:		

Required Attendees:

Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Pao, William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Freire, Maria (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Anderson, James (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Marks, Peter (FDA/CBER)

Optional Attendees:

Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood,

Central Account; Awwad, David (NIH/NIAID) [C]; Zottoli, Jessica; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, Dorina (FNIH) [T]; Hardesty, Rebecca (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Carver, Trea (NIH) [C]; Lowy, Douglas (NIH/NCI) [E]; **b6** Cheryl Melencio is inviting you to a scheduled Zoom meeting. Join Zoom Meeting b6 Meeting ID: b6 Password: **b6** One tap mobile US (New York) b6 US (Germantown) Dial by your location US (New York) US (Germantown) US (Chicago) US (San Jose) US (San Jose) US (Tacoma) US (Houston) Meeting ID: Password: **b6** Find your local number: b6

Gretchen (NIH/OD) [E]; Zanellato, Ann; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Li, Rose; FNIH

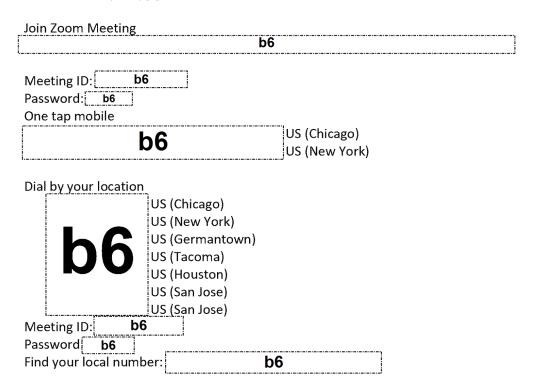
From:		IH) [T] [/O=EXCHANGELABS/OU			
		)/CN=RECIPIENTS/CN=CD9E70	2FCF28414883D0	)B6996D677257-	WHOLLEYD]
Sent:	5/18/2020 8:31:46				
To:	Wholley, David (FNI	IH) [T] [/o=ExchangeLabs/ou=E	xchange Adminis	trative Group	
		)/cn=Recipients/cn=cd9e702fc			
	(NIH/NCATS) [E]	<b>b6</b> Collins, F	rancis (NIH/OD) [		; Corey, Larry
	b6	; Disbrow, Gary (OS/ASPR)		b6	Dolsten, Mikael
	b6	Erbelding, Emily (NI	H/NIAID) [E]	b6	Fauci, Anthony
	(NIH/NIAID) [E]	<b>b6</b> Hudson, T	homas [	b6	; James, Stephanie (FNIH) [T]
	b6 ;	Johnson, Robert (OS/ASPR/BA	RDA)	b6 ;	Kramer, Lynn
	b6	; Lane, Cliff (NIH/NIAID)	[E] <b>b6</b>	; Marks,	Kramer, Lynn Peter (FDA/CBER)  Mascola, John
	b6	; Marston, Hilary (NIH,	,	80	7
	b6	; Meeker, David	b6 N	Лenetski, Joseph	(FNIH) [T] 66 ;
	Pangalos, Mene	b6	; Pao, William	b6	Paul, Steve
	b6	; Perlmutter, Roger	b6	; Plump,	Andy
	b6	Rasi, Guido	b6	Reed, Johr	h <b>b6</b> Rouse,
	Doris <b>b6</b>	]; Santos, Michael (FNIH) [T]	b6	Skovronsky, (	Daniel
	b6	Stein, Peter (FDA/	CDER)	b6 ;	Stoffels, Paul
	b6	; Tabak, Lawrence (NIH/OD			essey, Rupert
	b6	; Virgin, Skip <b>b6</b>	, Woodcock, J	lanet (FDA/CDER	)
	<b>b6</b>	; Young, John	b6 b6	Colvis,	Christine (NIH/NCATS) [E]
	b6	; Desrosiers, Betsy	b6	); Hı	ughes, Eric
	b6	); Jansen, Kathrin	00	į, Kurina, r	⁄lichael (NIH/NCATS) [E]
	b6	; Lowy, Douglas (NCI)	b6 Re	ead, Sarah (NIH/I	NIAID) [E]
	b6	; Freire, Maria (FNIH) [T]		Adam, Stacey (	
		varez@deloitte.com]; Anderso			
					stratton@deloitte.com]; Tolman,
		loitte.com]; Tountas, Karen (FI	NIH) [T] [	<b>b6</b> ; Wac	htel, Jonathan
	[jwachtel@deloitte	.com]; Rachel Ramoni	b6	Plenge, Robert	b6 Talley,
	Michael [	b6 ; Cavaleri, Ma	arco	b6	; Messonnier, Nancy
	(CDC/DDID/NCIRD/		s, Gary (NIH/NHL	· - · /   L - J	<b>b6</b> ; Gadbois, Ellen
		changeLabs/ou=Exchange Adr			
	. ,		e6f248268d2ede	c566c26c2a-gadl	poisel]; Culp, Michelle (NIH/OD)
	[E] <b>b6</b>	Tsai, John	b6		
CC:	Barasch, Kimberly (			rrus-Shaw, Cyndi	
			6 Conr	ad, Patricia (NIH)	'NIAID) [E]
	b6	; Hoffstetter, Renata (FI	NIH) [T <u>]</u>	<b>b6</b> ; lb	erdemaj, Vaide
	b6	; Lagos, Enrique (NI	H/NCATS) [E] [	b6	; McManus, Ayanna
	(NIH/OD) [E]	i, ivicient	cio, cheryi (i ivii i)	וויז מס	i Frotasiewicz, Aim
	<b>b6</b>	; Simon, Dina (NIH			nomas, Ashley (FDA/CDER)
	<b>NO</b>	Wood, Gretchen (		b6	Sepulveda, Dorina (FNIH) [T]
	b6	; FNIH Central Account [FN			
	Zottoli, Jessica L		er, Ashley (NIH/O		b6 ]; Gladman, Jordan
	(NIH/OD) [E]				illejos zenteno, Carlos [JRDUS]
	b6	Dimishkov, Roxanne (NIH/			; Burklow, John (NIH/OD)
	[E] <b>b6</b>	Wolinetz, Carrie (NIH/	· · · · · · · · · · · · · · · · · · ·		; Myles, Renate (NIH/OD) [E]
	b6	; Hallett, Adrienne (NIH/OD	* - * *		Chen, Helen
		e.com]; Lowy, Douglas (NIH/NC			zer, Abbey (FNIH) [T]
	, fa	; Gorman, Greta (FNIH) [T]	b6	]; Dana Carluccio	)
	<u>b</u>	6			
Code in the	ACTIV/ D = === D	uku anakin ja adambir Toon AA	-tin-44		
Subject:	ACTIV Response Par	rtnership Leadership Team Me	eting #4		i
Location:	Ĺ	b6			
Chauh.	C/2/2020 4:00:00 B	Ν.Δ			
Start:	6/3/2020 4:00:00 P				
End:	6/3/2020 5:30:00 P	IVI			
Show Time As:	. busy				

## Required Attendees:

Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Freire, Maria (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Rachel Ramoni; Plenge, Robert; Talley, Michael; b6 ; Cavaleri, Marco; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Gibbons, Gary (NIH/NHLBI) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]

## Optional Attendees:

(CDC/DDID/NCIRD/OD); Gibbons, Gary (NIH/NHLBI) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E] Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Simon, Dina (NIH/OD) [C]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]; FNIH Central Account; Li, Rose; Zottoli, Jessica; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Elsaid, Olivia; Castillejos zenteno, Carlos [JRDUS]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Burklow, John (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Chen, Helen; Lowy, Douglas (NIH/NCI) [E]; Meltzer, Abbey (FNIH) [T]; Gorman, Greta (FNIH) [T]; Dana Carluccio



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Attachments:	a5401-d03-activ-0	051620.doc	x; ACTIV_Therapeutics	s-Clinical_MP Sub	o-Group Meeting 18May	2020_Key Tal	keaways.pd

Dear ACTIV Outpatient mAbs Writing Team,

Please find attached the notes from today's meeting that Elizabeth did a great job in capturing. While I know we would have liked to make more forward headway, I do think our conversations put us on the right path to take the next step forward.

## Per the action items:

- Karen and Lisa are going to discuss the statistical parameters and they are going to try and capture that is a summary for the synopsis that we need for Wednesday's meeting with the Steering Committee that includes Janet Woodcock and others who will want to weigh in.
- Ajay and Paul were going to work on getting some of the Lilly data together to help us determine if we should have two primary endpoints: one virologic and one symptomatic. Or whether we are safer leaving the virologic endpoint as secondary as it is currently written.

In addition, we wanted to set another meeting of these team for tomorrow. I have discussed with Karen and Lisa and they think they could have some thoughts together for the group's response by 4pm tomorrow. **Would this group be able to meet from 4-5pm ET tomorrow?** 

Finally, the ACTG team that has been working on the base protocol would like to hear any other feedback not covered in the action items above from the group, so if you all can review and be ready to provide thoughts or send them in redline and comments ahead of the meeting, that would be perfect. (Document attached once again for ease of reference.)

Once again, thank you all for being willing to come together and get this protocol revised to fit the capacity needs of this new venture!

Thanks, Stacey

Stacev J. Adam, PhD

Director, Cancer

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Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] 5/19/2020 1:16:52 AM Sent: **b6** ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange To: Vincent, Mike Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Bascles, Lionel ; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry Desrosiers , Betsy b6 Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura **b6**; Srinivasan, Badhri **b6**; Wachtel, Jonathan [jwachtel@deloitte.com]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm] CC: Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Kenny, Dermot Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Garner, Carlos **b6** ; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric

b6 } Jansen, Kathrin b6 } Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John **b6** ]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Carluccio, Dana b6 ; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny b6 ; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose b6 ; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy ______b6 _____; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin b6 ; Hamilton, Nancy b6 ; Minnich, Beth
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[bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Victoria Davey [/o=ExchangeLabs/ou=Exchange

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End:	5/19/2020 2:00:00 PM						
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Required	every Tuesday and Friday from 9:00 AM to 10:00 AM Vincent, Mike; Stein, Peter (FDA/CDER); Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim						
Attendees:	(NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhri; Wachtel, Jonathan; Qashu, Felicia						
Optional	Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gail (NIH/NHLBI) [E]; Garner, Carlos; Colvis, Christine						
Attendees:	(NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] 6 6 5; Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] 6 6 ; Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich						
Dear Colleagueach topic! Be	ues, We have an interesting agenda (attached) for this call and look forward to the discussion surrounding est, Karen						
ACTIV: Acce	elerating COVID-19 Therapeutic Interventions and Vaccines						
Dear Clinical	Trial Capacity Working Group members,						
have agreed thareas of need, understand that	n of this working group making rapid progress on identified action items and other activities, the co-chairs nat it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify and to determine next steps. We ask that you make every effort possible to join each of these meetings, but at at times you may have competing priorities. To place a hold on your calendar, please accept this meeting response; later you can decline an individual meeting if you have a conflict.						
An agenda an	d other meeting materials, as needed, will be distributed prior to each call.						
With best rega Karen	ards,						
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Dear Colleagues, We have an interesting agenda (attached) for this call and look forward to the discussion surrounding each topic! Best, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards, Karen

Karen H. Tountas, PhD Scientific Program Manager Foundation for the National Institutes of Health

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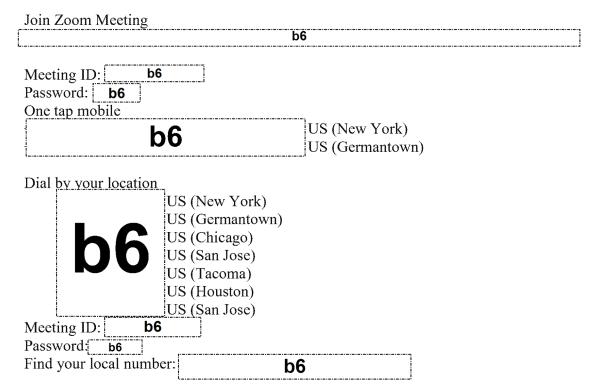
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Sent:	5/19/2020 2:23:05 AM
Sent: To:	
Subject: Attachments:	ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #11 Therapeutic information request form-v9-clean.docx; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_19May2020 Meeting Guide.pdf
Location:	b6
Start: End: Show Time As:	5/19/2020 5:00:00 PM 5/19/2020 6:00:00 PM Tentative
Required Attendees:	Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees:	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; b6  Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] b6; Rose Li Central Account

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for tomorrow's call.

- 1. Slides with topics and agenda internal.
- 2. Updated Company RFI/Survey for final review.

Thanks, Stacey



From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	5/19/2020 2 <u>:23:07 AM</u>
To:	Eric Hughes <b>b6</b> ; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa];
	Ruxandra Draghia-Akli b6 , Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel <b>b6</b> ; Colvis,
	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John    b6   Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike
	b6 ; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];
	Vincent, Michael b6 Keith Gottesdiener b6 Elliott Levy
	b6 ; Wung, Peter /US! b6 ; Koroshetz, Walter (NIH/NINDS) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner
	b6 ; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
CC:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc] Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
CC.	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	Maria [rosalvarez@deloitte.com]; Salathin, Carla   b6
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	b6 ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account
	[FNIH@roseliassociates.com]
Subject:	Materials for ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #11
Attachments:	ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_19May2020 Meeting Guide.pdf; Therapeutic
	information request form-v9-clean.docx
Dear ACTIV T	K-Clinical Agent Prioritization Subgroup,
	tached the materials for tomorrow's call.
	with topics and agenda internal.
2. Upda	ted Company RFI/Survey for final review.
<b>-</b>	
Thanks,	
Stacey	
n. *	XDS WA
Stacey J. Ad	
Director, Car Research Par	
Direct:	
21100th	<b>b6</b>   Mobile: <b>b6</b>
Join Zoom Me	eeting
	b6
!	

Meeting ID: b6 Password: b6
One tap mobile US (New York) **b6** US (Germantown) Dial by your location US (New York) US (Germantown) US (Chicago) US (San Jose) US (Tacoma) US (Houston) US (San Jose) Meeting ID: Password: **b6** b6 Find your local number:

From:	Adam, Stacey (FNIH) [T] [/					
	•	RECIPIENTS/CN=DCD875F	-0679648859E	[1CF101C0943414-ADAMSJ4]		
Sent:	5/19/2020 2:32:19 AM					
То:	Judy Currier [/o=Exchange					
	1	ecipients/cn=890082c7c	1e34902b0f53	35320cd16650-jscurrier.m]; Eric Hughes		
	<u>b6</u>			Sandeep Menon		
	b6			)) [E] [/o=ExchangeLabs/ou=Exchange		
	Administrative Group (FYD	DIBOHF23SPDLT)/cn=Reci	ipients/cn=7b4	45059209b4468bb4ba02b0dfbbb3e4-proso	:ham];	
	Read, Sarah (NIH/NIAID) [I	E] [/o=ExchangeLabs/ou=	Exchange Adr	ministrative Group		
	(FYDIBOHF23SPDLT)/cn=R	ecipients/cn=527b16003	8004a199ae6	e0bac2226099-readsa]; Price, Dionne (FDA	/CDER)	
	[/o=ExchangeLabs/ou=Exc	hange Administrative Gr	oup			
	(FYDIBOHF23SPDLT)/cn=R	ecipients/cn=a583eced8	42c44b18bb61	fcd3820bee21-priced.fda]; Rubin, Daniel B.		
	(FDA/CDER) [/o=Exchange	Labs/ou=Exchange Admi	nistrative Gro	up		
	· · · · · · · · · · · · · · · · · · ·			28f929042aad-RUBIND.fda]; Farley, John		
	(FDA/CDER) [/o=Exchange	-				
	· · · · · · · · · · · · · · · · · · ·			1fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Pri	ce	
	1		b6			
		b6		Eron, Joe	!	
	<b>b6</b> ; Jav		[F] [/o=Eycha	ingeLabs/ou=Exchange Administrative Grou	ın	
	i I			nigetabs/ou=Exchange Administrative Grot 95d7aa1327c4-javanarc]; Roa, Jhoanna	ıρ	
				3507 da 1327 c4-javariarcj, Noa, Jiloariila		
	[/o=ExchangeLabs/ou=Exchange Administrative Group					
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; <b>b6</b> ; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group					
	(FYDIBOHF23SPDLT)/cn=R					
CC:	Demarcus b6			] [/o=ExchangeLabs/ou=Exchange Administ		
				b750753cd5a14f93-tountaskh]; Wachtel, Jo	nathan	
	=	=		arker, Ashley (NIH/OD) [E]		
	[/o=ExchangeLabs/ou=Exc	hange Administrative Gr	oup			
	(FYDIBOHF23SPDLT)/cn=R	ecipients/cn=306b22444	66140faa95aa	aaafe06ebd70-parkeras]; Jhoanna Roa		
	h6	Eron, Joseph J Jr	b6	; Smith, David		
	b6	Paul Klekotka	b6	]; Ajay Nirula b6		
	*	L				
Subject:	<b>HOLD for Potential: ACTIV</b>	TX-Clinical Neutralizing r	nAb Outpatier	nt MP Writing Team Meeting		
Location:		b6				
i	L			i		
Start:	5/19/2020 8:00:00 PM					
End:	5/19/2020 9:30:00 PM					
Show Time As:	-					
JIIOW TIIIIC AS.	Tentative					
				A 6: 1		
Required		<del>-</del> .		an, Michael (NIH/NIAID) [E]; Read, Sarah		
Attendees:	(NIH/NIAID) [E]; Price, Dio	nne (FDA/CDER); Rubin, I		/CDER); Farley, John (FDA/CDER); Karen Ly	nn Price;	
			b6			
		b6	; Eron	, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa,	Jhoanna;	
	b6; Kim, Pe	ter (NIH/NIAID) [E]				
Optional	Demarcus; Tountas, Karen	(FNIH) [T]; Wachtel, Jon	athan; Elizabe	th Kim; Parker, Ashley (NIH/OD) [E]; Jhoani	na Roa;	
Attandage		avid: Paul Klokotka, Aiav				

Dear ACTIV-2 Writing Team,

Please save this time if you can for our next writing team meeting. While I am still waiting on a few critical confirmations since majority can make it, I want to go ahead and block it off.

An agenda will be send once we have the necessary participants confirmed.

Thanks,

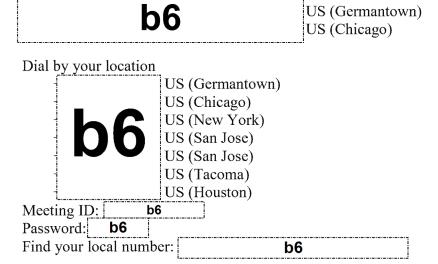
Stacey

Join Zoom Meeting	
	6
Meeting ID: <b>b6</b> Password: 934707 One tan mobile <b>b6</b>	US (Germantown) US (Chicago)
Dial by your location  US (Germantown) US (Chicago) US (New York) US (San Jose) US (San Jose) US (Tacoma) US (Houston)	
Meeting ID: <b>b6</b>	
Password: <b>b6</b>	
Find your local number: <b>b6</b>	

From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]						
Sent:	5/19/2020 2:32:20 AM						
To:	Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier						
	b6 ; Eric Hughes b6 LaVange, Lisa M b6 ;						
	Sandeen Menon   Proschan Michael (NIH/NIAID) [F]   P6						
	Read, Sarah (NIH/NIAID) [E] b6 Rubin,  Daniel B. (FDA/CDER) b6 Rubin,						
	Daniel B. (FDA/CDER) b6 Farley, John (FDA/CDER) b6 ; Karen Lynn						
	Price b6						
	b6 Eron, Joe						
	b6 ; Javan, Arzhang (NIH/NIAID) [E] b6 ; Roa, Jhoanna   b6						
	b6 Kim, Peter (NIH/NIAID) [E] b6 ; Jonathan Li b6 ; Marks,						
	Gilbert (OS/ASPR/BARDA) (CTR) b6						
CC:	Demarcus b6 Tountas, Karen (FNIH) [T] b6 ]; Wachtel, Jonathan						
	[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]						
	[/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa						
	Eron, Joseph J Jr b6 Smith, David						
	b6 ; Paul Klekotka b6 Ajay Nirula b6 ; Elsaid,						
	Olivia [oelsaid@deloitte.com]; Robert Jan Benschop b6 Lei Shen   b6						
Subject:	Confirmed: ACTIV TX-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting						
Attachments:	ACTIV Therapeutics-Clinical mAb outpatient MP 19May2020 Agenda.pdf						
Location:	<b>b6</b>						
Start:	5/19/2020 8:00:00 PM						
End:	5/19/2020 9:30:00 PM						
Show Time As:	Busy						
Required	Adam, Stacey (FNIH) [T]; Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID)						
Attendees:	[E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER);						
	Karen Lynn Price; b6						
	b6 , Joe; Javan, Arzhang						
	(NIH/NIAID) [E]; Roa, Jhoanna; <b>b6</b> ; Kim, Peter (NIH/NIAID) [E]; Jonathan Li; Marks, Gilbert						
	(OS/ASPR/BARDA) (CTR)						
Optional	Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa;						
Attendees:	Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen						
Dear ACTIV	V-2 Writing Team,						
This meeting	x is now confirmed. We should have guarum with meanle coming a little late or leaving a little						
_	g is now confirmed. We should have quorum with people coming a little late or leaving a little						
early, but wi	th the necessary overlap.						
Please see th	e suggested attached agenda. Please let me know if you have additions or amendments.						
Thanks,							
,							
Stocov							
Stacey							
Join Zoom M	Meeting						
[	b6						

Meeting ID:[ b6 Password: **b6** One tap mobile US (Germantown) b6 US (Chicago) Dial by your location US (Germantown) US (Chicago)
US (New York)
US (San Jose)
US (San Jose) US (Tacoma) US (Houston) Meeting ID: b6 Password: b6 Find your local number: b6

From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	5/19/2020 2:32:20 AM
To:	Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier
	b6 , Eric Hughes b6 , LaVange, Lisa M   b6
	Sandeep Menon b6 ; Proschan, Michael (NIH/NIAID) [E] b6
	Read, Sarah (NIH/NIAID) [E] b6 ; Price, Dionne (FDA/CDER) b6 ; Rubin,
	Daniel B. (FDA/CDER) b6 ; Farley, John (FDA/CDER) b6 Karen Lynn
	Price 66 prairies 56 prairies
	b6 Eron, Joe
	b6 Javan, Arzhang (NIH/NIAID) [E] b6 ]; Roa, Jhoanna b6
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CC:	\
CC.	1
	[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa
	b6; Eron, Joseph J Jrb6; Smith, Davidb6; Paul Klekotkab6; Ajay Nirulab6
	<b>b6</b> ; Paul Klekotka <b>b6</b> ; Ajay Nirula <b>b6</b>
Subject:	HOLD for Potential: ACTIV TX-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting
Location:	b6
Start:	5/19/2020 8:00:00 PM
End:	5/19/2020 9:30:00 PM
Show Time As:	Busy
Required	Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah
Attendees:	(NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price
Attendees.	b6
į	b6 ; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna
أ	Languaga and an anguaga and an anguaga anguaga an anguaga an anguaga an anguaga an anguaga an anguaga an anguag
Optional	<b>b6</b> Kim, Peter (NIH/NIAID) [E]; Jonathan Li Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa;
-	
Attendees:	Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula
Dear ACTIV	V-2 Writing Team,
Please save t	this time if you can for our next writing team meeting. While I am still waiting on a few critical
	as since majority can make it, I want to go ahead and block it off.
Commination	is since majority can make it, I want to go ancad and block it off.
An agenda w	vill be send once we have the necessary participants confirmed.
Thanks,	
i manns,	
C.	
Stacey	
Join Zoom M	Meeting
	b6
Meeting ID	h6
Meeting ID:	
Password:	
One tap mob	pile



From:	Young, John b6
Sent: To:	5/19/2020 12:06:52 PM Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
10.	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC:	Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Buchman, Tim (OS/ASPR/BARDA) (CTR)
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Carlos O Garner
	b6 ; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Elizabeth Kim
	[elkim@deloitte.com]; Elliott Levy b6 Eric Hughes b6 ;
	b6 Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Higgs, Elizabeth (NIH/NIAID)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; <b>b6</b> Keith Gottesdiener <b>b6</b> ; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw];
	Lucas Smalldon b6 ; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc];
	Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp];  Naimish Patel   b6   Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras];
	Poole, Mike   b6   Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Rose
	Li Central Account [FNIH@roseliassociates.com]; Ruxandra Draghia-Akli b6 ]; Salathin, Carla
	b6 Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Michael
	b6 Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie
	(NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Wholley, David (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Wung, Peter /US
Subject:	<b>b6</b>   RETACTIVETX-Clinical Agent Prioritization Subgroup Meeting #11
•	
Hi Stacey	
Thanks for si antibodies:	haring the materials. Some additional points of consideration for the SARS-CoV-2 neutralizing
	h 1
	ν4
Best regards	
7.1	
John	
On Tue 10 M	May 2020 at 04:24, Adam, Stacey (FNIH) [T] <b>b6</b> wrote:
On 1 uc, 19 f	May 2020 at 04:24, Adam, Stacey (FNIH) [T] <b>b6</b> wrote:

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,
Please find attached the materials for tomorrow's call.
<ol> <li>Slides with topics and agenda internal.</li> <li>Updated Company RFI/Survey for final review.</li> </ol>
Thanks,
Stacey
Join Zoom Meeting b6
Meeting ID b6 Password: b6 One tap mobile US (New York) US (Germantown)
Dial by your location  US (New York) US (Germantown) US (Chicago) US (San Jose) US (Tacoma) US (Houston) US (San Jose)  Meeting ID: b6  Password: b6 Find your local number: b6

From:	Adam, Stacey (FNIH) [T] [/O= (FYDIBOHF23SPDLT)/CN=REC					
Sent:	5/19/2020 1:23:59 PM	IFIENTS/CN-DCD6/3F	00/9048839610	F101C0545414	-ADAM334]	
To:	Judy Currier [/o=ExchangeLal	ns/ou=Exchange Admir	nistrative Group			
	(FYDIBOHF23SPDLT)/cn=Reci			20cd16650-isc	urrier.ml: Eric Hu	ghes
	b6	LaVange, Lisa M	b6	Sandeep M		855
	b6	Proschan, Micha				ige
	Administrative Group (FYDIB					
	Read, Sarah (NIH/NIAID) [E] [	/o=ExchangeLabs/ou=	Exchange Admin	istrative Group	)	
	(FYDIBOHF23SPDLT)/cn=Reci	pients/cn=527b16003	8004a199ae6e0l	bac2226099-re	adsa]; Price, Dion	ine (FDA/CDER)
	[/o=ExchangeLabs/ou=Excha	nge Administrative Gro	oup			
	(FYDIBOHF23SPDLT)/cn=Reci	pients/cn=a583eced84	12c44b18bb6fcd	3820bee21-pri	ced.fda]; Rubin, [	Daniel B.
	(FDA/CDER) [/o=ExchangeLab	_				
	(FYDIBOHF23SPDLT)/cn=Reci			⁶ 929042aad-RU	BIND.fda]; Farley	, John
	(FDA/CDER) [/o=ExchangeLab	_				
	(FYDIBOHF23SPDLT)/cn=Reci	pients/cn=40b4c4456l		7bcaa09bc-FAF	LEYJ.fda]; Karen	Lynn Price
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İ	b6 Javan	<b>b6</b> , Arzhang (NIH/NIAID)	TETT70-Evehang	ol abs/ou=Evch	ango Administrat	ivo Group
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	Group (FYDIBOHF23SPDLT)/c	n=Recipients/cn=40c0	4fef6f1e46f5b75	50753cd5a14f9	3-tountaskh]; Wa	achtel, Jonathan
	[jwachtel@deloitte.com]; Eliz	zabeth Kim [elkim@de	loitte.com]; Park	ker, Ashley (NIF	I/OD) [E]	
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Optional	Demarcus; Tountas, Karen (F			kim; Parker, As	niey (NIH/OD) [E	j; inoanna Roa;
Attendees:	Eron, Joseph J Jr; Smith, Davi	u; Paul Kiekotka; Ajay I	virula			

Dear ACTIV-2 Writing Team,

This meeting is now confirmed. We should have quorum with people coming a little late or leaving a little early, but with the necessary overlap.

Please see the suggested attached agenda. Please let me know if you have additions or amendments.

Thanks,

Stacey

Join Zoom Meeting

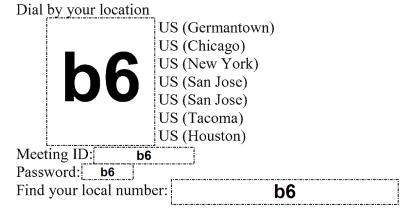
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	[jwachtel@deloitte.com]; Eliz	abeth Kim [elkim@del	loitte.com]; Parke	er, Ashley (NIH/OD) [E]		
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	<b>b6</b>	Paul Klekotka	b6 b6	Ajay Nirula	b6	Elsaid,
	Olivia [oelsaid@deloitte.com]	j		1		
Subject:	RE: Confirmed: ACTIV TX-Clini	=	Outpatient MP W	riting Team Meeting		
Attachments:	ACTIV Therapeutics-Clinical m					
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Dear ACTIV-2 Writing Team,

Please see the suggested attached agenda.

In addition, I am circulating a draft of the protocol with some comments from our Lilly colleagues. Looking forward to seeing you all in about an hour.

Thanks,

Stacey

Stacey J. Adam, PhD Director, Cancer Research Partnerships

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Subject:	Initial Follow-up to A	CTIV TX-Clinical	Agent Prioriti	zation Subgro	up Meeting #11		
Attachments:	ACTIV_Therapeutics-	Clinical_AP Sub	-Group Meeti	ng 19May2020	)_Key Takeaway	rs.pdf	

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Thank you all for a productive meeting today. I am glad we were able to finalize the RFI/Survey for the companies. We are well into building the REDCap data capture platform. We will share with you all the link once it is done.

Thank you as well for your feedback on the mAbs. Many of you have already gotten back to me with nominations for the committee, so I will like follow up individually with those who have expressed interest and if we do not fully meet our 6-8, I will then reach out again to the broader group.

For your reference, please find attached the high level notes for the meeting. The formal complete summary will be sent tomorrow.

Thanks, Stacey

Stacey J. Adam, PhD Director, Cancer Research Partnerships

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From:	Adam, Stacey (FNIH) [T]	[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP						
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	DO	; Paul Klekotka <b>b6</b> ; Ajay Nirula <b>b6</b> Elsa	ıid,					
	Olivia [oelsaid@deloitte	e.com]; Robert Jan Benschop [benschop_robert@lilly.com]; Lei Shen b6	7					
Subject:	Follow-up from ACTIV T	X-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting	1					
Attachments:		nical_ACTIV TX-Clinical Neutralizing mAb Outpatient MP 19May2020_Key Takeaways.pd	if;					
	ACTIV_200519.pdf; ACT	IV2_MasterProtocolWritingMeeting_May19_LisaKaren_Final.pdf; 5401 Protocol Synops	sis					
	051920v2.docx							

Dear ACTIV TX-Clinical mAb Outpatient WT,

Thank you all for a very productive meeting today. I think we covered a lot of group, and while I know we still have a lot more to cover, we made some progress!

I am attaching the notes that our Deloitte colleague Olivia was kind enough to capture for us, and I have attached both Lisa and Karen's and Michael's slide set for the group's reference. Please let me know if you have questions on any of these.

In addition, I am attaching a protocol synopsis that the ACTG team was kind enough to draft up to space me splicing together slides tomorrow for the presentation to the ACTIV mAb Master Protocol Steering Committee who will meet to review tomorrow.

For this group, I would like to get our next meeting on the books. **Time may be tight tomorrow due to a number of other meetings. Does the group want to shoot for an evening call, staring around 5:30 or 6pm ET?** Please let me know what might work for you and I will see if we can get quorum.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

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From:	Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
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	<b>b6</b> Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth
	[elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@DELOITTE.com];
	Prabhavathi Fernandes b6 Diamond, Michael b6 Rose Li
	b6 Dana Carluccio b6 ; Lagos, Enrique (NIH/NCATS)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
	Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
	(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D  b6
Subject:	RE: ACTIV Preclinical working group (Friday meeting)

Attachments: PRECLINICAL_Working Group_Agenda_0520_d1.pptx; ACTIV PRECLINICAL_Animal Model Inventory_20200514 jpm.xlsx Hi all, Please find attached some materials to aid in our discussion today. The first document contains the agenda as well as our WG's objectives and timeline. Also attached is the Animal Model Inventory. Please let us know if you have any questions. Best, ----Original Appointment----From: Menetski, Joseph (FNIH) [T] Sent: Tuesday, April 14, 2020 6:49 PM b6 <u>To: Menetski, Joseph (FNIH) [T];</u> Barıc, Ralph; Ottinger, Elizabeth JUOTTN (NIH/NIAID) [E]; Deming, Damon ; Parker, Ashley (N Christine (NIH/NCATS) [E]; Hewitt (NIH/NCATS [E]; COTVIS (FDA/CDER); [ Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA) Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski Subject: ACTIV Preclinical working group (Friday meeting) When: Friday, May 22, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada). Where: **b6** Holding time Joseph Menetski is inviting you to a scheduled Zoom meeting. Join Zoom Meeting **b6** Meeting ID: b6 Password: One tap mobile US (New York) **b6** US (Chicago) Dial by your location US (New York) US (Chicago) US US US (Houston) US (San Jose)

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<u>U</u>S (San Jose)

Meeting ID:

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/20/2020 4:02:38 PM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes b6 b6 ; LaVange, Lisa M ; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price b6 Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner ; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative CC: Demarcus Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras] Subject: ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review Attachments: 5401 Protocol Synopsis 051920v3.docx Location: b6 5/20/2020 5:00:00 PM Start: End: 5/20/2020 6:00:00 PM Show Time As: Tentative Required Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E];

Attendees: Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O

Optional Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]

Attendees:

Dear ACTIV TX-Clinical Master Protocol mAbs Steering Committee,

Please find attached the synopsis of the outpatient protocol for review at our meeting today. This was assembled by the ACTG group based on our writing team conversations and then edited a bit by Lisa and Karen for the statistical sections.

This document is NOT ready to share beyond this group yet, but could be gotten ready in short turn if needed for the company summit, Janet. We will just need to know when that is.

Finally, we will be discussing the selection of the inpatient network for the companion protocol today.

Thanks,

Stacey

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	; Eron, Joseph J Jr b6 Smith, David				
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	Olivia [oelsaid@deloitte.com]; Robert Jan Benschop   <b>b6</b> ; Lei Shen   <b>b6</b>				
Subject:	RE: Follow-up from ACTIV TX-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting				
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it looks like w	e can get about ¾ of the group together tonight. Would the group still like to meet from 6-7pm ET.				
In the though	t that I think we will want to, I am going to send a calendar hold with a zoom link just in case.				
Thanks,					
STacey					
Stacey J. Ad	am. PhD				
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From: Adam, Stacey (FNIH) [T]

**Sent:** Tuesday, May 19, 2020 11:05 PM

Subject: Follow-up from ACTIV TX-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting

Dear ACTIV TX-Clinical mAb Outpatient WT,

Thank you all for a very productive meeting today. I think we covered a lot of group, and while I know we still have a lot more to cover, we made some progress!

I am attaching the notes that our Deloitte colleague Olivia was kind enough to capture for us, and I have attached both Lisa and Karen's and Michael's slide set for the group's reference. Please let me know if you have questions on any of these.

In addition, I am attaching a protocol synopsis that the ACTG team was kind enough to draft up to space me splicing together slides tomorrow for the presentation to the ACTIV mAb Master Protocol Steering Committee who will meet to review tomorrow.

For this group, I would like to get our next meeting on the books. **Time may be tight tomorrow due to a number of other meetings. Does the group want to shoot for an evening call, staring around 5:30 or 6pm ET?** Please let me know what might work for you and I will see if we can get quorum.

Thanks, Stacey

Stacey J. Adam, PhD Director, Cancer

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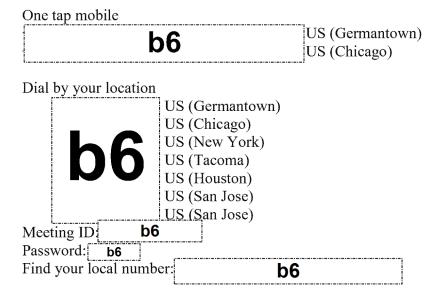


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	Olivia [oelsaid@deloitte.com]; Robert Jan Benschop <b>b6</b> Lei Shen <b>b6</b>					
Subject:	Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3					
Attachments:	5401 Protocol Synopsis 051920v3.docx					
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	Olivia [oelsaid@deloitte.com					6		
Subject:	RE: Confirmed: ACTIV TX-Clir	nical mAb Outpatient W	T Meeting-3					
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	that has been working wi	•		-	s for this protoco	oi would like		
to offer the a	ttached thoughts for the gr	oup's consideration o	n tonight's ca	ıll.				
Also, attachin	g again the updated synop	sis that was discussed	with the mA	b Steering Comn	nittee earlier tod	ay.		
Thanks,								
Stacey								
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	b6 LaVange, Lisa M b6 ; Read, Sarah (NIH/NIAID) [E]							
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Demarcus  b6   Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	b6 Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan							
	[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]							
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Subject:	Re: [EXTERNAL] Re: ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review							
<b>,</b>	[=							
I support Libb	y's recommendation. It will be important that the lead network consider this their top priority for							
	on and managing the supportive networks like PETAL. I also particularly support that NIAID hold the IND.							
Regards,								
riogaras,								
Carl								
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	FINE LALL (AUL) (AUL) (AUL) (FINE LA							
	s, Elizabeth (NIH/NIAID) [E]" b6							
	esday, May 20, 2020 at 4:54 PM							
To: "Adam, S	Stacey (FNIH) [T]" b6 "Bozzette, Sam (NIH/NCATS) [E]" b6							
"Butterton, J	Joan" ₹ <b>b6</b> Judy Currier <b>b6</b> , Eric Hughes							
	b6 "LaVange, Lisa M" b6 "Read, Sarah (NIH/NIAID) [E]"							
<u> </u>	Karen Lynn Price <b>b6</b> "Higgs, Elizabeth (NIH/NIAID) [E]"							
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Jonathan" <j< th=""><th>wachtel@deloitte.com&gt;, Elizabeth Kim <elkim@deloitte.com>, "Parker, Ashley (NIH/OD) [E]"</elkim@deloitte.com></th></j<>	wachtel@deloitte.com>, Elizabeth Kim <elkim@deloitte.com>, "Parker, Ashley (NIH/OD) [E]"</elkim@deloitte.com>							

**Subject:** [EXTERNAL] Re: ACTIV TX-Clinical Master Protocol mAbs Steering Committee - ACTIV2 Synopsis Review

**EXTERNAL EMAIL:** Use caution before replying, clicking links, and opening attachments.

Dear ACTIV mAb SC Colleagues,

I would like to propose that INSIGHT be identified as the lead network for the inpatient mAb study, with NIAID holding the IND, with the proviso that they work collaboratively with the PETAL network, companies, our SC etc. as one protocol team. We would also want assurance that this will be their priority.

Someone commented that INSIGHT was overcommitted and I do not think this is the case, they have an 10,000 outpatient COVID observational study which can contribute enrollment to the inpatient study through early identification of COVID patients needing hospitalization, and over 300 sites globally and no interventional studies at this time though European sites are supporting ACTT 2 (though not yet). They have done a lot of thinking on their inpatient protocol for hIVIG and this could be leveraged as a started point just as we leveraged the ACTG draft protocol.

The addition of PETAL sites domestically to the domestic sites in INSIGHT would be an advantage. The addition of the entire VA Hospital system could be a huge advantage as well. With so many sites we should enroll quickly.

Finally, the INSIGHT network is already operational with an excellent track record in registrational trials. I worry a bit that the NHLBI new network of networks will take some time to stand up operationally and would prefer the USG held the IND.

Hoping I'm not biased by my NIAII	D origin, but I am comfortable that INSIGHT can lead	I this.
Thanks,		
Libby		
From: b6		
When: 1:00 PM - 2:00 PM May	20, 2020	
Subject: ACTIV TX-Clinical Mast	ter Protocol mAbs Steering Committee - ACTIV2	Synopsis Review
Location:	he	

Dear ACTIV TX-Clinical Master Protocol mAbs Steering Committee,

Please find attached the synopsis of the outpatient protocol for review at our meeting today. This was assembled by the ACTG group based on our writing team conversations and then edited a bit by Lisa and Karen for the statistical sections.

This document is NOT ready to share beyond this group yet, but could be gotten ready in short turn if needed for the company summit, Janet. We will just need to know when that is.

Finally, we will be discussing the selection of the inpatient network for the companion protocol today.

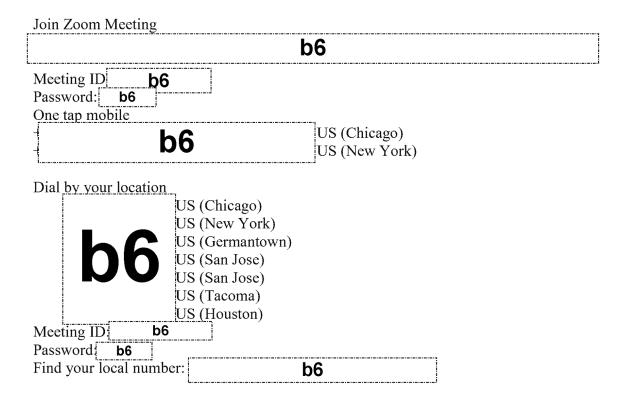
Thanks,

Stacey

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	b6 ; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange							
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	Vincent, Michael <b>b6</b> ; Elliott Levy							
	b6 Wung, Peter /US b6 Koroshetz, Walter (NIH/NINDS) [E]							
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	<b>b6</b> Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]							
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative							
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	Maria [rosalvarez@deloitte.com]; Salathin, Carla <b>b6</b>							
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account							
Carlota A.	[FNIH@roseliassociates.com]							
Subject:	Materials for ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12							
Attachments:	ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_21May2020 Meeting Guide.pdf; 2020-05-19_TX-							
	Clinical_WG_Agent_Prioritization_Committee_Meeting-Summary.pdf							
Daniel TV Clinia	al A anna Daireithia tì an Calamana							
Dear IX-Clinic	al Agent Prioritization Subgroup,							
	tached the formal summary from yesterday's meeting.							
In addition, pl	ease find the slides for tomorrow's meetings. Please let me know if you have any amendments or							
additions.								
Thanks,								
Stacey								
,								
Stacey J. Ad	om. PhD							
Director, Car								
Research Par								
Direct:								
DHOVE	b6 Mobile: b6							

Stacey Adam is inviting you to a scheduled Zoom meeting.



Sent: \$5/21/2020 1:50:05 AM   Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDBOHE23SPDLT)/cn=Recipients/cn=27b15:0038004199ase6obac2226099-reads3); Ruxandra Draghia-Akli   Section   Recipients/cn=27b15:0038004199ase6obac2226099-reads3); Ruxandra Draghia-Akli   Section   Recipients/cn=28rb17/cn=Recipients/cn=user257cb36(), Nalmish Patel   Section   Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb15/cn=28rb17/cn=Recipients/cn=28rb15/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb15/cn=28rb17/cn=Recipients/cn=28rb15/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb15/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Recipients/cn=28rb17/cn=Rec	From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
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D6   Wung, Peter /US   D6   Koroshetz, Walter (NH/NINDS) [E]     Jo=ExchangeLabs/ou=Exchange Administrative Group     (FYDIBOHE23SPDLT)/cn=Recipients/cn=68338dd7cdd328986961f1548c5ec6-koroshetzw); Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group     MIH/NIAID   [E] [/o=ExchangeLabs/ou=Exchange Administrative Group     Jo6   Goff, David (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group     FYDIBOHE23SPDLT/Jcn=Recipients/cn=036113c7be0H27897d1294cfbb99c10-goffdc]     Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group     FYDIBOHE23SPDLTJ/cn=Recipients/cn=050113F2dc4a427ea3d34f1e072f8cd7-menetskijp]; Alvarez, Rosa     Maria [rosalvarez@deloitte.com]; Salathin, Carla   D6     Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group     (FYDIBOHE23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe60ebd70-parkeras]; Wholley, David (FNIH) [T]     Jo=ExchangeLabs/ou=Exchange Administrative Group     (FYDIBOHE23SPDLT)/cn=Recipients/cn=049e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)     T] Jo=ExchangeLabs/ou=Exchange Administrative Group     (FYDIBOHE23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon		
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FYDIBOHE 23SPDLT]/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner   b		
CC:		(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
CC:   Elizabeth Kim [elikim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FVDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla   b6   Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FVDIBOHF23SPDLT)/cn=Recipients/cn=306b2244d65140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FVDIBOHF23SPDLT)/cn=Recipients/cn=20702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)   T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FVDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon   b6   j; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FVDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon   Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FVDIBOHF23SPDLT)/cn=Recipients/cn=24114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account   FNIH@roseliassociates.com  (FVDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account   FNIH@roseliassociates.com  Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12 Attachments: 2020-05-19 TX-Clinical_WG_Agent_Prioritization_Committee_Meeting-Summary.pdf; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_21May2020 Meeting Guide.pdf		
CC: Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4ad27ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla b6 Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b224d466f140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon b6 ], Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [FNIH@roseliassociates.com]  Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12 Attachments: 2020-05-19_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting-Summary.pdf; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_21May2020 Meeting Guide.pdf  Location: 66  Start: 5/21/2020 3:00:00 PM Show Time As: Tentative  Required Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NIACTS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Eliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NIHBI) [E] Opt		<b>b6</b> ; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp); Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Salathin, Carla   b6   Parker, Ashley (NIH/OD) [E] /Jo=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon   b6   ]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832240acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [FNIH@roseliassociates.com]  Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12 Attachments: 2020-05-19_TX-Clinical Agent_Prioritization_Committee_Meeting-Summary.pdf; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_21May2020 Meeting Guide.pdf  Location:   b6		(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
Maria [rosalvarez@deloitte.com]; Salathin, Carla Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon    b6	CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLTI)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLTI)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLTI)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon		Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]		Maria [rosalvarez@deloitte.com]; Salathin, Carla b6
[/o=ExchangeLabs/ou=Exchange Administrative Group [FYDIBOHF23SPDLT]/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl [FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group [FYDIBOHF23SPDLT]/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group [FYDIBOHF23SPDLT]/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [FNIH@roseliassociates.com]  Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12 Attachments: 2020-05-19_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting-Summary.pdf; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_21May2020 Meeting Guide.pdf  Location: b6  Start: 5/21/2020 3:00:00 PM End: 5/21/2020 4:00:00 PM Show Time As: Tentative  Required Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine Attendees: (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E] Optional Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; b6 Attendees: Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula		Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
[/o=ExchangeLabs/ou=Exchange Administrative Group [FYDIBOHF23SPDLT]/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl [FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group [FYDIBOHF23SPDLT]/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [b6]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group [FYDIBOHF23SPDLT]/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [FNIH@roseliassociates.com]  Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12 Attachments: 2020-05-19_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting-Summary.pdf; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_21May2020 Meeting Guide.pdf  Location: b6  Start: 5/21/2020 3:00:00 PM End: 5/21/2020 4:00:00 PM Show Time As: Tentative  Required Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine Attendees: (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E] Optional Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; b6 Attendees: Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula		
FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)   T]   /o=ExchangeLabs/ou=Exchange Administrative Group   FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon   b6   j. Walker, Paula (NIH/NINDS) [E]   /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E]   /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account   FNIH@roseliassociates.com   FNIH@roseliassociates.com   Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12   Attachments: 2020-05-19_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting-Summary.pdf; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_21May2020 Meeting Guide.pdf   Death		
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon		
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon    b6   ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange   Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];   Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group   (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account   [FNIH@roseliassociates.com]		
b6   ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account (FNIH@roseliassociates.com)  Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12 Attachments: 2020-05-19_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting-Summary.pdf; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_21May2020 Meeting Guide.pdf  Location:   b6    Start: 5/21/2020 3:00:00 PM   End: 5/21/2020 4:00:00 PM   Show Time As: Tentative  Required		
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Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [FNIH@roseliassociates.com]  Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12  Attachments: 2020-05-19_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting-Summary.pdf; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_21May2020 Meeting Guide.pdf  Location: b6  Start: 5/21/2020 3:00:00 PM End: 5/21/2020 4:00:00 PM Show Time As: Tentative  Required Attendees: (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHAIBI) [E]  Optional Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; b6 Attendees: Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula		
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End: 5/21/2020 4:00:00 PM  Show Time As: Tentative  Required	Start.	5/21/2020 3:00:00 PM
Required Attendees:  Coptional  Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]  Optional  Attendees:  Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula		·
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Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the formal summary from yesterday's meeting. In addition, please find the slides for tomorrow's meetings. Please let me know if you have any amendments or additions.

Thanks, Stacey

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	(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC:	DeMarcus, Forrest b6 ; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh];
	Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa
	b6 ; Smith, David b6 ; Paul Klekotka b6
	Ajay Nirula b6 ; Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschop
	h6 : Lei Shen : h6
Subject:	Re: [EXTERNAL] RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3
•	
Thanks for the	e clarification. Then we should be good.
THOMAS TOT CIT	e darmouton. Then we should be good.
Candaan	
Sandeep	
From: "LaVa	nge, Lisa M" ₹ b6
	day, May 21, 2020 at 9:35 AM
	· · · · · · · · · · · · · · · · · · ·
To: Sandeep	
	b6 "Adam, Stacey (FNIH) [T]"
b6	Judy Currier <b>b6</b> Eric Hughes <b>b6</b>
"Read, Sarah	n (NIH/NIAID) [E]"   b6
,	b6 , "Rubin, Daniel B. (FDA/CDER)" b6 , "Farley, John
(FDA/CDER)'	V Di
(FDA) CDEK)	i b6 Karen Price D6
	h <b>G</b>
	DO
i	

"Wohl, David A"	b6	, "Fische	er, William A	. II"	b6	
"Javan, Arzhang (NIH/N	IAID) [E]"	b6	"Roa,	Jhoanna"	b6	
b6	"Kim, Peter	(NIH/NIAID) [	E]"[	b6 ,	Jonathan Li	
b6	] "Marks, Gilbert	t (OS/ASPR/B	ARDA) (CTR)"	b6	3	"Kozak, Marina
(OS/ASPR/BARDA)"	b6					
Cc: "DeMarcus, Forrest'	' b6		"Tountas, K	aren (FNIH) [T]'	' b6	
"Wachtel, Jonathan" < j	wachtel@deloitte	e.com>, Elizab	eth Kim <elk< td=""><td>im@deloitte.co</td><td>om&gt;, "Parker,</td><td>, Ashley</td></elk<>	im@deloitte.co	om>, "Parker,	, Ashley
(NIH/OD) [E]" ₹	b6	Jhoanna Roa	[	b6	, "Smith, [	David"
b6	Paul Klek	otka	b6	Ajay Nir	ula	b6 ,
"Elsaid, Olivia" <oelsaid< td=""><td>@deloitte.com&gt;,</td><td>Robert Jan B</td><td>enschop</td><td></td><td></td><td>Lei Shen</td></oelsaid<>	@deloitte.com>,	Robert Jan B	enschop			Lei Shen
b6	•					
Subject: RE: [EXTERNAL	RE: Confirmed:	ACTIV TX-Clin	ical mAb Ou	tpatient WT Me	eeting-3	
•	•			,	J	
I think we were thinking a	bout stopping rule	s based on syr	nptom resolut	ion in the phase	2 portion and	clinical endpoints
(hosp) in the phase 3 port						
earlier this week.						
From: Menon, Sandeep M	1	b6				
Sent: Thursday, May 21, 2	:					
To: Proschan, Michael (NI		b6	LaVa	nge, Lisa M	b6	Eron,
Joseph J Jr	<b>b6</b> A	dam, Stacey (F	NIH) [T]	<b>b6</b>	udy Currier	
b6	; Eric Hughes	b	6	Read, Sarah (N	IH/NIAID) [E]	
b6	Price, Dionne (FDA	√CDER) {	b6	Rubin,	Daniel B. (FDA	\/CDER)
b6	}; Farley, John (F		b6	; Karen	Lynn Price	
	<b>.</b>	b6				<u></u> j
b6	Wohl, David A	b6		Fischer, William		;=:=:=:=:=:=.
b6	i	hang (NIH/NIA	ID) [E]	b6	; Roa, Jhoar	<i>\</i> 0.00000000000000000000000000000000000
b6	Kim, Peter (NIH/I		b6	; Jonathan L	\	6
Marks, Gilbert (OS/ASPR/ <b>b6</b>	BARDA) (CTR) <u> </u> 	b6	Kozai	, Marina (OS/AS	PR/BARDA)	
Cc: DeMarcus, Forrest	<u>і</u> b6		as, Karen (FNI	ы\ (т) <del>[</del>		/achtel, Jonathan
<pre><jwachtel@deloitte.com></jwachtel@deloitte.com></pre>				L		b6
Jhoanna Roa	h6	Smith, David	t arker,	6	Paul Klekotka	
b6		b6	Flsaid (	Olivia <oelsaid@< td=""><td>deloitte.com&gt;</td><td>: Robert lan</td></oelsaid@<>	deloitte.com>	: Robert lan
Benschop b6		i Shen {	b6	100,00,00	acronologo (no	,
Subject: Re: [EXTERNAL] F	,	i		nt WT Meeting-3	3	
•			•	Ü		
Agree Mike and Lisa. Not	worried about the	stats rules, th	e basic questi	on is what we dis	scussed yester	day. Do we have
enough confidence in the	assay and the qua	ntitative cut of	fs and whethe	er it correlates to	the clinical er	ndpoint early
enough. I am assuming th	ne decision for futi	lity or efficacy:	stopping will b	e based on clini	cal endpoint (a	and not just the
viral load). Based on the	discussion yesterd:	ay, I heard that	we were not	sure that viral lo	ad correlates	with the clinical
endpoint.						
From: "Proschan, Micha	ael (NIH/NIAID) [[	Ξ]"	b6			
Date: Thursday, May 21	., 2020 at 8:52 Al	<b>М</b>				
To: "LaVange, Lisa M"	b6	"Eron	, Joseph J Jr"	l	o <b>6</b>	"Adam,
Stacey (FNIH) [T]"		ıdy Currier	b(	; ;	, Eric Hughes	
<b>b6</b>	, Sandeep N	\	b6			ah (NIH/NIAID)
L	J	i			.! '	•

[E]"		b6			, "Rubin, Daniel B.
(FDA/CDER)"	b6	, "Farley, Johr	(FDA/CDER)	)"   b6	·
				<u> </u>	<u></u>
		<b>b</b> 6			
		b6		, "V	Vohl, David A"
b6	, "Fisch	er, William A. II'		b6	"Javan, Arzhang
(NIH/NIAID) [E]'	b6	, "Roa, Jhoar	ına"	b	6
<b>b6</b> , "Kim, Peter (	(NIH/NIAID) [E]"	b6	Jonath	an Li	o6 "Marks,
Gilbert (OS/ASPR/BA	RDA) (CTR)"	b6	, "Kozak,	Marina (OS/ASP	R/BARDA)"
b6				r	
Cc: "DeMarcus, Forre	:		-	en (FNIH) [T]" [	b6
"Wachtel, Jonathan"	<jwachtel@delo< td=""><td></td><td></td><td></td><td></td></jwachtel@delo<>				
(NIH/OD) [E]"[	b6	, Jhoanna Roa		),	"Smith, David"
b6	i	Klekotka (	b6	Ajay Nirula	
"Elsaid, Olivia" < oelsa	<u>aid@deloitte.co</u> 	<u>m</u> >, Robert Jan Ber	nschop[	b6	>, Lei Shen
b6					_
Subject: [EXTERNAL]	RE: Confirmed:	ACTIV TX-Clinical n	nAb Outpatie	ent WT Meeting-3	3
I think the guestion is a	uhathar wa aauld	l stan aprily far affica	ev es well es s	tanning april for f	utility. That could cortainly
			-		utility. That could certainly ter only 50 people. At the
			_		o 3, so you would have to
see a very large z-score	_	-	Juliually for th	e 2-3core 13 close t	o 3, so you would have to
see a very large 2 score	to stop that carr	y for efficacy.			
Mike.					
From: LaVange, Lisa M	b6				
Sent: Thursday, May 2:	L				
To: Eron, Joseph J Jr	b6	; Adam, S	tacey (FNIH) [	T] <b>b6</b>	; Judy Currier
b6	}; Eric Hugh	nes b6		Sandeep Menon	
b6	۶; Pros	chan, Michael (NIH/	NIAID) [E]	b6	>; Read, Sarah
(NIH/NIAID) [E]	b6	Price, Dionne (FDA,	<u> </u>	b6	Rubin, Daniel B.
(FDA/CDER)	b6	Farley, John (FDA/	CDER)	b6	Karen Lynn Price
	W. L. B	b6		- L - NACILI - A L	
b6	Wohl, David			scher, William A. I	
b6		, Arzhang (NIH/NIAIC IIH/NIAID) [E]	/) [□] b6	<b>b6</b>   Jonathan Li	Roa, Jhoanna <b>b6</b>
<b>b6</b> Marks, Gilbert (OS/ASP		, t		Marina (OS/ASPR/	i ·
<b>b6</b>	iy banbay (e my.		i NOZak,	Wallia (OS/ASI IV	DANDAJ
Cc: DeMarcus, Forrest	b6	; Tountas	, Karen (FNIH)	) [T] <b>b6</b>	; Wachtel, Jonathan
<jwachtel@deloitte.co< td=""><td></td><td>I</td><td></td><td>· L</td><td></td></jwachtel@deloitte.co<>		I		· L	
Jhoanna Roa	b6	; Smith, David	be	Pau	ıl KTekotka
b6	Ajay Nirula	b6	; Elsaid, Ol	ivia < <u>oelsaid@del</u> d	oitte.com>; Robert Jan
Benschop	b6		o6		
Subject: RE: Confirmed	l: ACTIV TX-Clinica	al mAb Outpatient W	T Meeting-3		
Th:	S			- i	
				•	opping dose arms or entire
agents, having little to Lisa	go on at this poin	t in terms or what be	est hi edicts NC	ospitalizations.	
usa					
From: Eron, Joseph J Jr					
Sent: Wednesday, May		Л			
To: Adam, Stacey (FNII	•	Judy Currier		b6 };	Eric Hughes
	7 L L L L L L L L L L L L L L L L L L L	i sady carrier	i	:::::::::::::::::::::::::::::::::::::	

b6	; LaVange, Lis	a M <b>b</b> 6	<u> </u>	Sandeep M	enon		
b6	; Prosch	an, Michael (NIH/	NIAID) [E]	b	6	; Read, Sar	ah
(NIH/NIAID) [E]		rice, Dionne (FDA	·	b6		]; Rubin, Dar	
(FDA/CDER)	b6 ; F	Farley, John (FDA)	CDER)	b6		Caren Lynn P	rice
		b6					]
b6	Wohl, David A	b6		; Fischer, Will		:	
b6	; Javan, A	rzhang (NIH/NIAII		b6		a, Jhoanna	b6
b6	Kim, Peter (NIH	/NIAID) [E]	b6	Jonath	·	b6	
Marks, Gilbert (OS/ASPR)	BARDA) (CTR) {	b6	}; Koza	ak, Marina (O	S/ASPR/BAF	RDA)	
b6			/r.s				
Cc: DeMarcus, Forrest	b6	i'		JIH) [T]		£	el, Jonathar
<jwachtel@deloitte.com< td=""><td></td><td></td><td><u>om</u>&gt;; Parke</td><td>r, Asniey (NiF</td><td>·</td><td>b6</td><td>) </td></jwachtel@deloitte.com<>			<u>om</u> >; Parke	r, Asniey (NiF	·	b6	) 
Jhoanna Roa	b6	; Smith, David (	Logid		Paul Kl		art lan
	; Ajay Nirula		), Elsaiu, 26	Olivia < <u>oelsa</u>	<u>iiu@ueioitte</u>	z.com>, Robe	ert Jari
Subject: RE: Confirmed: A	, <u> </u>	i		3			
Jubject. NE. commined. 7	CITY IX Clinical	nab outpatient v	/ i wiccung	3			
Here is my question for t	he groun – esneci	ally Michael John	andlisa				
My question is whether t				nilar to the fu	tility analys	is listed helo	w - the
reason I ask is we have ve		•	•				
would have substantial p	,	•			. ,		
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			,				
<ul> <li>If the Phase 2 po</li> </ul>	rtion of the Clinica	al mAb protocol is	used for d	ose finding, tl	his mav be c	hallenging w	ith respect
-	l (number of treat	•			•		-
	riate to establish						
	inuation of a dose	•					
high doses due to		c.g. 55 fdth	o, man ii	patients, or	to anow car	i, discortant	
mgn doses due t	, saicty midnigs.						

Joe Eron MD Professor of Medicine University of North Carolina at Chapel Hill School of Medicine

b6

Sent: Wednesday, Ma			,	,				
<b>To:</b> Judy Currier {	l	b <b>6</b>	_j; Eric Hughes	į	b6	}}; LaV	'ange, Lisa N	Λ
b6	: Sand	eep Menon {	h	6	>: Prose	chan. Mich	ael (NIH/NI	AID) [E]
	Re	ead, Sarah (Nii	H/NIAID) [E]	b6	>; F	rice, Dionr	ne (FDA/CDI	ER)
b6	<b>&gt;</b> ; I	Rubin, Daniel	B. (FDA/CDER)		b6	; Farle	y, John (FD <i>A</i>	\/CDER)
	Ka	ren Lynn Price	\		b <b>6</b>			
		b6				Wohl, Da	vid A	
L.C		Fischer, Willia	m A. II [	b6		; Eron, Jo	seph J Jr	
<b>b</b> 6			ng (NIH/NIAID)					b6
b6	; Kim	, Peter (NIH/N	IIAID) [E]	b6	>; Jonat	han Li	b6	
Marks, Gilbert (OS/AS								
b6		L		·· <del>-</del>				
Cc: DeMarcus, Forrest	t {	b <b>6</b>	Tounta	s, Karen (FN	IIH) [T]	b6		htel, Jonatha
<jwachtel@deloitte.c< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></jwachtel@deloitte.c<>								
Jhoanna Roa			Eron, Joseph J J					
b6		Paul Klekotka	r		Ajay Nirul			Elsaid,

Olivia < <u>oelsaid@deloitte.com</u> >; Robert Jan Be	nschop {	b6	; Lei Shen	b6
Subject: RE: Confirmed: ACTIV TX-Clinical mAl	o Outpatient W	T Meeting-3		
Dear mAb Outpatient WT,				
The FDA team that has been working with AC to offer the attached thoughts for the group's				is protocol would like
Also, attaching again the updated synopsis tha	at was discusse	d with the mAb	Steering Committee e	arlier today.
Thanks, Stacey				
Stacey J. Adam, PhD Director, Cancer Research Partnerships Direct: b6   Mobile: b6				
Join Zoom Meeting  Meeting ID: b6	b6			
Meeting ID: b6 Password: b6 One tap mobile				
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Dial by your location  US (Germantown) US (Chicago) US (New York) US (Tacoma) US (Houston) US (San Jose) US (San Jose)				
Meeting ID: <b>b6</b>				
Password b6 Find your local number: b	6			

From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] Sent: 5/21/2020 3:26:14 PM To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel ; Cohen, Myron ; Corey, Larry Desrosiers, Betsy Dickens, Jim (NIH/NCATS) [C] b6 Doroshow, James (NIH/NCI) [E] ; Goff, David (NIH/NHLBI) [E] Kurilla, b6 ; Nayak, Seema (NIH/NIAID) [E] Michael (NIH/NCATS) [E] ; Parker, Ashley b6 ; Payton, Manizhe (NIH/NIAID) [E] (NIH/OD) [E] [ Resnansky, Laura Srinivasan, Badhri ; Stein, Peter (FDA/CDER) b6 Wachtel, Jonathan [jwachtel@deloitte.com]; Qashu, Felicia (NIH/OD) [E] b6 Vincent, Mike b₆ CC: Colvis, Christine (NIH/NCATS) [E] j; Jansen, Kathriní Lowy, ; Young, John ; Read, Sarah (NIH/NIAID) [E] ; Adam, Stacey (FNIH) [T] ; Anderson, Margaret [marganderson@deloitte.com]; Carluccio, Dana [ ; Melencio, Cheryl (FNIH) [T] ; Collins, Francis (NIH/OD) [E] Gonzalez, Nina James, Stephanie (FNIH) [T] [ningonzalez@deloitte.com]; Heaton, Penny Menetski, Joseph (FNIH) [T] ; Li, Rose Santos, Michael (FNIH) [T] ; Tuvesson, Nancy ]; Wholley, David (FNIH) [T] ີ່; Minnich, Beth ; Criffield, Robin Katz, Rebecca (NIH/NCATS) [E] **b**6 Stratton, Benjamin [bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Victoria Davey : Sizemore, Christine (NIH/FIC) [E] Jintanat Ananworanich Kenny, Dermot ! ; Weinmann, Gail (NIH/NHLBI) [E]_ Mensah, George (NIH/NHLBI) [E] ; Garner, Carlos ; Reid, Nancy (NIH/OD) [C] Joshua (NIH/OD) [E] Moschetti, Justin (NIH/OD) [E] f-----]; Culp, Michelle (NIH/OD) [E] b6 Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hughes, Eric Hamilton, Nancy Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting Clinical Trial Capacity Working Group Meeting Agenda_05222020.pdf; ACTIV Protocol Tracker 05212020.pdf Attachments: Location: Start: 5/22/2020 1:00:00 PM 5/22/2020 2:00:00 PM End: Show Time As: Busy Recurrence: Weekly every Tuesday and Friday from 9:00 AM to 10:00 AM Required Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Attendees: Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Qashu, Felicia Optional Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gail (NIH/NHLBI) [E]; Mensah, George (NIH/NHLBI) [E]; Attendees: Garner, Carlos; Denny, Joshua (NIH/OD) [E]; Reid, Nancy (NIH/OD) [C]; Gebo, Kelly (NIH/OD) [G]; Moschetti, Justin (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] b6 ; Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues, Attached is the Agenda. Please note that we will be hearing from the <u>All of Us</u> program and how they might be useful for implementing ACTIV protocols. In addition, per a request from Tuesday's meeting, attached is the ACTIV Protocol Quick Reference Tracker – thanks to Jonathan and his colleagues for creating this! At present there are three ACTIV protocols, all in the treatment category. CTC Recommendations Committees have been established for the ACTIV-1 and ACTIV-2 protocols to-date and integration with the protocol development and lead network operations teams will take place in the very near future. Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards, Karen

Karen H. Tountas, PhD Scientific Program Manager Foundation for the National Institutes of Health

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b(	3
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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] 5/21/2020 3:26:44 PM Sent: To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Vincent, Mike ; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Bascles, Lionel Corey, Larry **b6** ]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy ; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura ; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wachtel, Jonathan [jwachtel@deloitte.com]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang] CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Jintanat Ananworanich ; Walker, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e577497e37b244168bd76c0b8827ca71-Robert.Walk]; Mason, Robin (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77156b112de94c439dbccb6894954618-Robin.Mason]; Hughes, Eric **b6** ; Criffield, Robin **b6** ; Hamilton, Nancy Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth Mueller-Reichenstein, Petra b6 Quadros, Nora Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group Quadros, Nora (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana b6 ; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose ; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH)

	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy    b6
Subject: Attachments: Location:	ACTIV Clinical Trial Capacity Working Group - reporting meeting Clinical Trial Capacity Working Group Meeting Agenda_05262020.pdf  b6
Start: End: Show Time As:	5/26/2020 1:00:00 PM 5/26/2020 2:00:00 PM Busy
Recurrence:	Weekly
Required Attendees:	every Tuesday and Friday from 9:00 AM to 10:00 AM Vincent, Mike; Goff, David (NIH/NHLBI) [E]; Bascles, Lionel; Corey, Larry; Cohen, Myron; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Garner, Carlos; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzine; Qashu, Felicia; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan,
Optional Attendees:	Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Mensah, George; Weinmann, Gail Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Jintanat Ananworanich; Walker, Robert (OS/ASPR/BARDA); Mason, Robin (OS/ASPR/BARDA); Hughes, Eric; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein, Petra; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] b6  Zoe (NIH/NHLBI) Hill [C] b6  Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E]  b6  Carluccio, Dana; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS)  [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John
know that BA	nes, Attached is the Agenda for the Clinical Trial Capacity Working Group agenda. I am please to let you RDA (Biomedical Advanced Research and Development Authority, U.S. Dept of Health and Human join the meeting to talk about their CRO relationships. With best regards, Karen
assess the nee	Trial Capacity WG members, This will extend our full working group calls through the end of May. We'll d for further meetings at the end of the month. Many thanks for your participation! Karen
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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] 5/21/2020 3:27:04 PM Sent: To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Garner, Carlos b6 ; Bascles, Lionel ; Vincent, Mike ; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative b6 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry ; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy ; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wachtel, Jonathan [jwachtel@deloitte.com]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang] CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Kublin MD, MPH, James ; Ferguson, Sue <u>b6</u>; Kenny, Dermot Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Criffield, Robin ; Hamilton, Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth ; Mueller-Reichenstein, Petra b6 ]; Quadros, Nora Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana ; James, Stephanie (FNIH) [T] Heaton, Penny [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy

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	b6 ; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative						
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine						
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	b6 Jansen, Kathrin b6 Lowy, Douglas (NCI)						
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	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group						
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	b6						
Subject:	ACTIV Clinical Trial Capacity Working Group - reporting meeting						
Attachments:	Clinical Trial Capacity Working Group Meeting Agenda_05292020.pdf						
Location:	b6						
Start:	5/29/2020 1:00:00 PM						
End:							
	5/29/2020 2:00:00 PM						
Show Time As:	Busy						
Recurrence:	Weekly						
	every Tuesday and Friday from 9:00 AM to 10:00 AM						
Required	Garner, Carlos; Bascles, Lionel; Vincent, Mike; Payton, Manzine; Cohen, Myron; Corey, Larry; Davey, Victoria;						
Attendees:	Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla						
	Mike; Nayak, Seema (NIH/NIAID) [E]; Qashu, Felicia; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan,						
	Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Mensah, George; Weinmann, Gail						
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Optional	Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Kublin MD, MPH, James; Ferguson, Sue; Kenny, Dermot;						
Attendees:	Gonzalez, Nina; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein,						
	Petra; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] <b>b6</b> ; Zoe (NIH/NHLBI) Hill [C]						
	b6 ; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E]						
	b6 [Carluccio, Dana; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T];						
	Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric;						
	Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John						
Colleagues –	Attaching the agenda for the call. Best, Karen						
Dear Clinical	Trial Capacity WG members, This will extend our full working group calls through the end of May. We'll						
	ed for further meetings at the end of the month. Many thanks for your participation! Karen						
assess the nec	a for further meetings at the end of the month. Many thanks for your participation: Karen						
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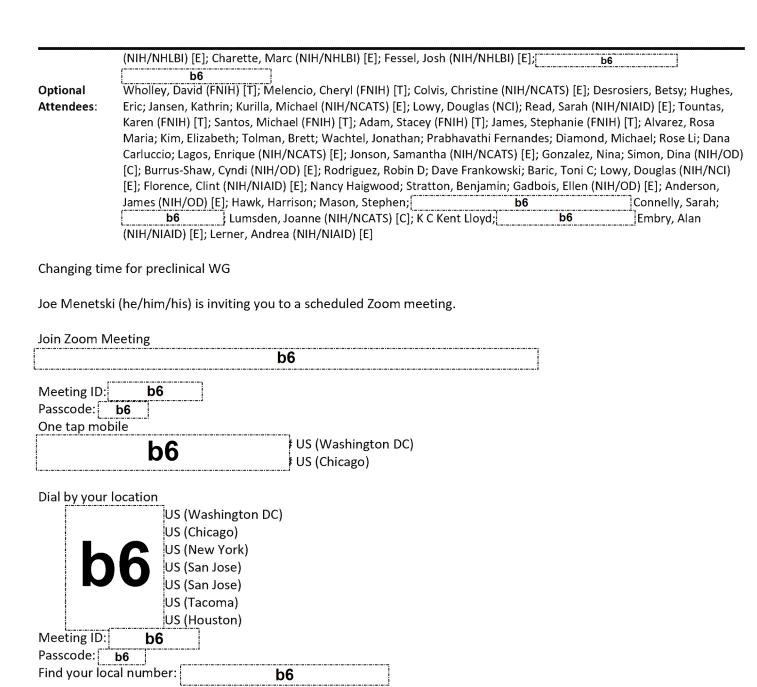
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į	Doming Damon (EDA/CDED)								
	b6   Parker, Ashley (NIH/OD) [E] b6  ; Collins, Francis								
	(NIH/OD) [E] [ b6 ; Adams, Peter (OS/ASPR/BARDA)								
	b6 Rao, Srinivas /US b6 Anderson, James (NIH/OD) [E]								
	; Tomas Cihlar b6 ; Qashu, Felicia (NIH/OD) [E]								
CC:	Nancy Haigwood b6 Diamond, Michael b6 Wholley, David (FNIH) [T]								
	Austin, Christopher (NIH/NCATS) [E] 66 Melencio, Cheryl (FNIH) [T]								
	j, Colvis, Christine (Mill/MCAT3) [L]								
	he hugnes, Eric be j; Jansen, Kathrin								
	b6 ]; Read, Sarah (NIH/NIAID) [E] b6 ]; Tountas, Karen (FNIH) [T] b6 ]; Adam, Stacey (FNIH) [T] b6								
	James, Stephanie (FNIH) [T] b6 ; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth								
	[elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com];								
	Prabhavathi Fernandes <b>b6</b> ; Rose Li <b>b6</b> ; Dana Carluccio								
	j, Lagos, Enrique (Nin/NCATS) [E]								
	(NIH/NCATS) [E] <b>b6</b> Gonzalez, Nina [ningonzalez@deloitte.com]; Simon, Dina (NIH/OD) [C	-]							
	b6   Burrus-Snaw, Cyndi (NiH/OD) [E]   b6   J. Kodriguez, Robin D   Lowy, Douglas (NIH/NCI) [E]								
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	Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group								
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Subject:	ACTIV Preclinical working group (Friday meeting)								
Location:	b6								
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Required Attendees:	<b>b6</b>								
Attenuees.									
	b6 Parker,								
	Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; b6 Adams, Peter								
	(OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]; Tomas Cihlar; Qashu, Felicia (NIH/OD) [E]								
Optional	Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T];								
Attendees:	Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam,								
	Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel,								
	Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha								
	(NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D;								
	Dave Frankowski; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Louise Pitt   <b>b6</b>	1							

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	(NIH/OD) [E]						
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Го:	Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group  (EVDIROHE23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-bildsal- <b>b6</b>
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; b6
	<b>b6</b> Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group
	[FYDIBOHF23SPDLT]/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai];
	Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine
	(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER)
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
	b6 Parker, Ashley (NIH/OD) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras];
	b6 ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative
	[
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas
	Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar
	( b6 USARMY MEDCOM b6 (USA) b6 ;
	Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc
	(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; <b>b6</b>
	b6
CC:	Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy
	<b>b6</b> ; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin
	[kathrin.jansen@pfizer.com]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T]
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T]
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T]
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria
	· · · · · · · · · · · · · · · · · · ·
	[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim,
	Elizabeth [elkim@deloitte.com]; Tolman, Brett [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan [jwachtel@deloitte.com]; Prabhavathi
	Fernandes b6 Diamond Michael b6 Rose Li

	b6	; Dana Carluccio	<b>D6</b>	; Lagos, Enrique (NIH/NCATS)
	[E] [/o=ExchangeLabs/ou=Exc	_		·
				1-lagoses]; Jonson, Samantha
	(NIH/NCATS) [E] [/o=Exchange			
	(FYDIBOHF23SPDLT)/cn=Recip			
	-		**	n=Recipients/cn=user3c2f486d];
	Simon, Dina (NIH/OD) [C] [/o=			•
				-simondm]; Burrus-Shaw, Cyndi
	(NIH/OD) [E] [/o=ExchangeLal	_		
	(FYDIBOHF23SPDLT)/cn=Recip	pients/cn=5bbac95b1f6e45	L4a299b318030c31f6	5-shawcy]; Rodriguez, Robin D
	<b>b6</b> Dave	Frankowski	b6	; antoinette_baric
		-	· ·	n=Recipients/cn=userb6b844cf];
	Douglas (NIH/NCI) [E] [/o=Exc			
				a-lowyd]; Florence, Clint (NIH/NIAID)
	[E] [/o=ExchangeLabs/ou=Exc	-		
			8/8/e844a///3295f	e-florencewc]; Nancy Haigwood
	[/o=ExchangeLabs/ou=Exchar	-	24 0 - 520 - 41 6 1-	Their and the Charles Destruction
				5-haigwoon.oh]; Stratton, Benjamin
		-	**	n=Recipients/cn=usere3ed7188];
	Gadbois, Ellen (NIH/OD) [E] [/			
				a-gadboisel]; Anderson, James
	(NIH/OD) [E] [/o=ExchangeLal		·	12 and an animal, Havely Hamison
				3-andersonjm]; Hawk, Harrison
	Mason, Stephen	b6	TUIBUNF253PULT // C	n=Recipients/cn=user280c84f8]; ; Connelly, Sarah
			VDIDOHE33CDDLT\/c	n=Recipients/cn=user3ed93bab];
				Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recip			
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	Ĺ			c49acac21cb83fd599d-embrya];
	Lerner, Andrea (NIH/NIAID) [6			
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Subject:	ACTIV Preclinical full working	group		
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	Untitled Attachment; Untitled	Attachment; Untitled Atta	chment; Untitled Att	achment; Untitled Attachment;
	Untitled Attachment; Untitled	Attachment; Untitled Atta	chment; Untitled Att	achment; Untitled Attachment;
	Untitled Attachment; Subgrou	up discussion of prediction o	of therapy resistance	from emerging viral sequence data;
	Untitled Attachment; Untitled	Attachment; Untitled Atta	chment; Untitled Att	achment; Untitled Attachment;
				achment; Canceled: ACTIV Preclinical
	full working group; Untitled A	ttachment; Untitled Attach	ment; Untitled Attac	nment
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Required Attendees:	Hild, Sheri (NIH/OD) [E];		DU	<u>-</u>
Attenuees.		hƙ		
		DU		; Parker,
	( Ashley (NIH/OD) [E];	b6	Adams, Peter (OS/AS	PR/BARDA); Rao, Srinivas; Qashu,
	Felicia (NIH/OD) [E]; Tomas C			<b>b6</b> (USA); Punturieri, Antonello
			i	2007 () Function, Antonomo



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/21/2020 4:14:59 PM Sent: To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, b6 ; Eisner, Mark | b6 Gottesdiener, Keith Hughes, Eric b6 ; Judy Currier Ruxandra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa b6 Levy, Elliot b6 ; Mellors, John V [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; **b6** ; Mellors, John W Menon, Sandeep b6 ; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish b6 ; Peppercorn, Amanda b6 ; Poole, Mike b6 Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group 

 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn

 b6
 Garner, Carl
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 Higgs, Elizabeth (NIH/NIAID) [E]

 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy ; Jansen, Kathrin **b6**; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group

		·		e6e304e34		au-dri.nelix.nj; Young,	John
	b6	; Bigg	s, Mary	b6	j; Butcher		<u></u> ;
	Demarcus	b6	Macone		b6	Melencio, Cheryl (FNII	H) [T]
	[/o=ExchangeLabs/d	ou=Exchange A	dministrative	Group			
	(FYDIBOHF23SPDLT)	)/cn=Recipients	s/cn=279e14	fa7428415b	b86087d08b628	e6f-melencioc]; Salath	in, Carla
	b6	; Tou	ıntas, Karen	FNIH) [T] [/	o=ExchangeLabs/	ou=Exchange Adminis	trative Group
	(FYDIBOHF23SPDLT	)/cn=Recipients	s/cn=40c04fe	f6f1e46f5b	750753cd5a14f93	3-tountaskh]; Menetsk	i, Joseph (FNIH) [T
	[/o=ExchangeLabs/d					1/	, , , , , , , , , , , , , , , , , , , ,
					a3d34f1e072f8ch	7-menetskijp]; James,	Stenhanie (FNIH)
	[T] [/o=ExchangeLab				434341100721000	// menetskijpj, james,	stephanie (TMT)
				•	45570577 - 2 - 2 d	1 :	
	•					1-jamesst]; Wachtel, J	
	_	_	_		_	Rosa [rosalvarez@delo	itte.comj;
	Gonzalez, Nina [/o=	-	_				
	(FYDIBOHF23SPDLT)					b6	; Rose
	Li Central Account [	FNIH@roseliass	sociates.com	]; Anderson	, Margaret [marg	anderson@deloitte.co	m]; Lucas
	Smalldon	b6		; Stratton	, Benjamin [bstra	tton@DELOITTE.com]	;
	<b>b6</b>	Mol	lica, Linda /L	7.0.0.0.0.0.0.0	b6	Qashu, Felicia (NIH,	
	[/o=ExchangeLabs/d	i		!			,
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	(NIH/NHLBI) [E] [/o=		-			teo quantumij, i attera	on, Amy
						Of mathemal, Caff Day	: /NULL/NULLIDI) [E]
					80413191065007	Of-pattersa]; Goff, Dav	ia (MH/MHLBI) [E]
	[/o=ExchangeLabs/d						
					97d1294cfbb99c1	LO-goffdc]; Rubin, Dan	iel B. (FDA/CDER)
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Subject:	ACTIV TX-Clinical W	orking Group <b>N</b>	leeting #7				
Attachments:	<b>ACTIV</b> Therapeutics	-Clinical Full Wo	orking Group	_21May202	20 Meeting Guide	.pdf	
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Required						DER); Draghia-Akli, Ru	
Attendees:						ge, Lisa; Levy, Elliot; M	
	Menon, Sandeep; Pa	arker, Ashley (N	NIH/OD) [E];	Patel, Naimi	ish; Peppercorn, A	Amanda; Poole, Mike;	Proschan, Michael;
	Read, Sarah; Santos	, Michael (FNIH	l) [T]; Shen, \	uan Li (FDA	/CDER); Stein, Pe	ter (FDA/CDER); Whol	ley, David (FNIH)
	[T]; Buchman, Tim (	OS/ASPR/BARD	A) (CTR); Col	lins, Sylva (I	FDA/CDER); Amar	nda Peppercorn; Garno	er, Carl; Higgs,
						thy; Reineck, Lora (NII	
						emy (NIH/NINDS) [E];	
	(NIH/OD) [E]	,	30,120,8, 140	3 (1111.1) 111.12.	o., [2], o. o, sc.	cmy (11m7) (11m05) [2])	oddioons, Elleri
Ontional		LI/NICATO\ [E], F	Dannasiana D	tau lancan	Kathrin, Kurilla	Michael (NIIII (NICATE)	[E], Loung Douglas
Optional						Michael (NIH/NCATS)	
Attendees:						lencio, Cheryl (FNIH) [	
	Tountas, Karen (FNI	H) [T]; Menetsl	ki, Joseph (FN	IIH) [T]; Jam	nes, Stephanie (FN	NH) [T]; Wachtel, Jona	than; Tolman,
	Brett; Alvarez, Rosa	; Gonzalez, Nin	a; Dana Carlı	iccio; Rose l	Li Central Accoun	t; Anderson, Margaret	; Lucas Smalldon;
	Stratton, Benjamin;	b	6	; Mollica,	Linda /US; Qashu	ı, Felicia (NIH/OD) [E];	Patterson, Amy
	(NIH/NHLBI) [E]; Go	ff, David (NIH/N	NHLBI) [E]	b6	Rubin, Da	u, Felicia (NIH/OD) [E]; aniel B. (FDA/CDER)	
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Thanks, Stacey

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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	5/21/2020 4:19:16 PM
To:	Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Eric Hughes
	<b>b6</b> ; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli
	b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel <b>b6</b> ; Colvis, Christine
	(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John
	b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike
	b6 ]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];
	Vincent, Michael <b>b6</b> ; Keith Gottesdiener <b>b6</b> ; Elliott Levy
	b6 ; Wung, Peter /US b6 ; Higgs, Elizabeth (NIH/NIAID) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner
	b6 Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	Maria [rosalvarez@deloitte.com]; Salathin, Carla
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
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	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	b6 ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account
	[FNIH@roseliassociates.com]
Subject:	RE: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12
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Thanks, Wa	lterl
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Stacey J. A	
Director, C	
Research P.	······································
Direct:	b6 Mobile: b6
Erom: Koros	shetz, Walter (NIH/NINDS) [E] <b>b6</b>
	· · · · · · · · · · · · · · · · · · ·
	day, May 21, 2020 11:30 AM
	tacey (FNIH) [T] <b>b6</b> ; Eric Hughes <b>b6</b> ; Read, Sarah (NIH/NIAID) [E]
i	6 ; Ruxandra Draghia-Akli b6 ; Mellors, John W b6 ; Naimish
Patel	b6 ; Colvis, Christine (NIH/NCATS) [E] b6 ; Young, John
	<b>b6</b> ; Stein, Peter (FDA/CDER) <b>b6</b> ; Poole, Mike
	<b>b6</b> ; Buchman, Tim (OS/ASPR/BARDA) (CTR) b6 Vincent,
Michael	<b>b6</b> ; Keith Gottesdiener <b>b6</b> ; Elliott Levy
i	Mung, Peter /US <b>b6</b> Higgs, Elizabeth (NIH/NIAID) [E]

h.C	; Carlos O Garner	b6	Goff, David (I	NIH/NHLBI) [E]
<b>b6</b>	i			
<pre><rosalvarez@deloitte.c< pre=""></rosalvarez@deloitte.c<></pre>	i m@deloitte.com>; Men com>; Salathin, Carla	etski, Joseph (FNIH)	1] <b>D6</b> b6	; Alvarez, Rosa Maria Parker, ; Melencio, Cheryl (FNIH) Walker, Paula (NIH/NINDS) [E] se Li Central Account
Ashley (NIH/OD) [E]	b6 };	; Wholley, David (FNI	H) [T]b6	; Melencio, Cheryl (FNIH)
[T] <b>b6 b6</b>	; Lucas Smalldon	b6	· Pos	Walker, Paula (NIH/NINDS) [E]
<pre><fnih@roseliassociate< pre=""></fnih@roseliassociate<></pre>	s.com>	MIND3/[L]	<b>bb</b> , NOS	e Li Central Account
Subject: RE: ACTIV TX-0	Clinical Agent Prioritizat	ion Subgroup Meetir	g #12	
Links to the most releva	ant part of the CTSAs—	Some of the Trial Inn	ovation are power	houses for clinical trials
(Duke/Vanderbilt? . T	· · · · · ·			
Center for Innovative	Trials in Children ar	nd Adults (TRIDEN	<u>(</u> (link is external)	•
	niversity and Vanderbilt I <b>rs:</b> Daniel K. Benjamir			n R. Bernard, M.D. (Vanderbilt)
Utah Trial Innovation	<u>ı Center</u> (link is externa	11)		
Institution: University Principal Investigato	of Utah r: Jonathan Michael D	ean, M.D.		
Johns Hopkins-Tufts	Trial Innovation Cen	ıter(link is external)		
			), Daniel E. Ford,	M.D. (Johns Hopkins), and Harry
Walter				
Original Appointme	ent			
From: Adam, Stacey (Fi				
<b>Sent:</b> Wednesday, May <b>To:</b> Fric Hughes: Read	•	Ruxandra Draghia-Ak	i: Mellors, John W	; Naimish Patel; Colvis, Christine
				OS/ASPR/BARDA) (CTR); Vincent,
			etz, Walter (NIH/N	INDS) [E]; Higgs, Elizabeth
Cc: Elizabeth Kim: Men	O Garner; Goff, David ( etski, Joseph (FNIH) [T];	мін/мньві) [Е] : Alvarez. Rosa Maria	: Salathin, Carla:	b6
				ucas Smalldon; Walker, Paula
, , , , , , , , , , , , , , , , , , , ,	, Jackie (NIH/NINDS) [E]	•		
•	cal Agent Prioritization 21, 2020 11:00 AM-12:0			Canada).
Where:		b6		
	Prioritization Subgroup,			
Please find attached th	e formal summary from	n yesterday's meeting	<b>5.</b>	
In addition, please find additions.	the slides for tomorrov	v's meetings. Please	let me know if you	u have any amendments or
Thanks, Stacey				

Join Zoom Meeting b6 b6 Meeting ID: Password: **b6** One tap mobile US (Chicago) **b6** US (New York) Dial by your location US (Chicago) US (New York) US (Germantown) US (San Jose) US (San Jose) US (Tacoma) US (Houston) Meeting ID: b6 Password: **b6** Find your local number: b6

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/21/2020 4:44:16 PM Sent: To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra b6 ; Eisner, Mark b6 Gottesdiener, Keith b6 ; Hughes, Eric b6 ; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa b6 Levy, Elliot b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364];
Menon, Sandeep | **b6** ; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; b6 ; Peppercorn, Amanda b6 Poole, Mike Patel, Naimish ; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/ Higgs, Elizabeth (NIH/NIAID) [E] (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John ; Biggs, Mary **b6** ; Butcher, Tina

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	(FYDIBOHF23S	PDLT)/cn=Recipier	nts/cn=5001af52	2dc4a427e	a3d34f1e07	2f8cb7-menetskijp]; James,	Stephanie (FNIH)
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	(FYDIBOHF23S	PDLT)/cn=Recipier	nts/cn=f0032ef6	2ca343dfb	4bf79577e2	laa8d1-jamesst]; Wachtel, Jo	onathan
						rez, Rosa [rosalvarez@deloi	tte.com];
		i [/o=ExchangeLab			•		
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	,		ssociates.com];			marganderson@deloitte.co	
	Smalldon	b6				bstratton@DELOITTE.com];	
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Subject:	ACTIV TX-Clinic	cal Working Group	Meeting #7				
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Attendees:						n; Melencio, Cheryl (FNIH) [T	
						ie (FNIH) [T]; Wachtel, Jonat	
						count; Anderson, Margaret;	
	Stratton, Benja	amin;	b6	Mollica,	Linda /US;	Qashu, Felicia (NIH/OD) [E]; I	Patterson, Amy
	(NIH/NHLBI) [E	]; Goff, David (NIH	/NHLBI) [E]	b6	Rub	Qashu, Felicia (NIH/OD) [E];   iin, Daniel B. (FDA/CDER)	
			L				
Dear ACTIV TX	(-Clinical WG,						
ooking forwa	ard to seeing y	ou all soon at the	e meeting. Ple	ase find a	ttached th	e slides for the meeting.	
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Γhanks,							
Stacey							
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/21/2020 4:44:18 PM Sent: To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra b6 Eisner, Mark b6 ; Gottesdiener, Keith b6 Hughes, Eric b6 ; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa b6 ; Levy, Elliot b6 Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep b6 Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish **b6** Peppercorn, Amanda **b6** ; Poole, Mike Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group 

 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn

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 Garner, Carl
 Higgs, Elizabeth (NIH/NIAID) [E]

 [/o=ExchangeLabs/ou=Exchange Administrative Group

 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy ; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, Johb6Biggs, Maryb6; Butcher, Tinab6

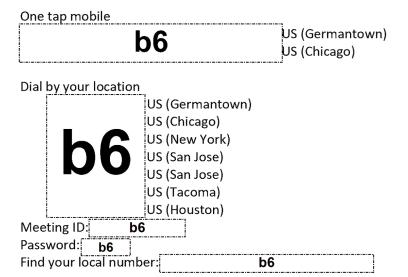
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Subject	t:	Slides for A	ACTIV TX-Cli	nical Workin	g Group Meeting #7			
Attach	ments:	ACTIV The	rapeutics-Cl	inical Full W	orking Group_21May2	:020 Meeting Gu	uide.pdf	
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Deal A	CIIV I	X-Clinical V	vo,					
Lookin	g forwa	ard to seei	ng vou all s	oon at the	meeting Please fine	d attached the	slides for the meeting.	
LOOKIII	B 101 W	ar a to seen	ing you am s	oon at the	meeting. Trease init	a attachea the	shaes for the meeting.	
Thank	S.							
Stacey								
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Password: b6
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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP] 5/21/2020 4:54:26 PM Sent: To: Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams) (USA)أ ; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group b6 [FYDIBOHF235PDLT]/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; b6 ; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Rao, Srinivas Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group CC: (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy Hughes, Eric **b6**; Jansen, Kathrin b6 Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@deloitte.com]; Prabhavathi Fernandes Diamond, Michael ; Dana Carluccio ; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses];

Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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	[/o=ExchangeLabs/ou=Exchange Administrative Group	
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	[bstratton@DELOITTE.com]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou	
Cubinet.	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-	-gadbolsei]
Subject: Attachments:	RE: ACTIV Preclinical working group (Tuesday meeting) s: 2020-05-20_Preclinical_WG_Summary_F1.docx	
Attacimients.	3. 2020-03-20_Freeimical_wd_Julimary_F1.docx	
Dear Preclinic	nical Working group members and attendees,	
	the minutes from yesterday's meeting attached. Thank you for a very inter	esting meeting and all of the work
you continue	ue to do for the ACTIV effort.	
Best regards,		
Joe and Rosa	Sa Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Comment of the Com	
Original A	I Appointment	
_	etski, Joseph (FNIH) [T]	
	day, April 14, 2020 6:43 PM	
To:	14y, April 14, 2020 0.45 PW	
		JSA); Menetski, Joseph (FNIH) [T];
Adams, Peter	1 (05)/10111/071110111/1	JSAJ, Merietski, Joseph (FMin) [1],
	<b>b</b> 6	
Parker, Ashle	ley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Rao, Srinivas; Qashu, Felicia	(NIH/OD) [E]; Tomas Cihlar
	Dina (NIH/OD) [C]; Florence, Clint (NIH/NIAID) [E]; Wholley, David (FNIH) [T	
	cio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; H	
	hael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; To	-
	NIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa	
	ntel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Ca	
	S) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Burrus-Shaw, Cy	
	inkowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Nancy Haigwood; Strat	
(NIH/OD) [E]		· · ·
Subject: ACTI	TIV Preclinical working group (Tuesday meeting)	
When: Wedn	dnesday, May 20, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US {	& Canada).
Where:	dnesday, May 20, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US 8 <b>b6</b>	
Changing time	me for preclinical WG	
Joseph Mene	netski is inviting you to a scheduled Zoom meeting.	
Join Zoom Me	Meeting	
	b6	
Meeting ID:	b6	
	b6	



From:	Michael Hughes	b6		
Sent:	5/21/2020 5:48:46 PM			
To:	(FYDIBOHF23SPDLT)/cn=   <b>b6</b> } { (FYDIBOHF23SPDLT)/cn=   <b>b6</b>	Proschan, Michael (NIH/NIA Recipients/cn=7b45059209l ;; Judy Currier [/o=Excha	648859e1cf101c0943414-adamsj4]; ID) [E] [/o=ExchangeLabs/ou=Exchar o4468bb4ba02b0dfbbb3e4-proschar angeLabs/ou=Exchange Administrativ	nge Administrative Group m]; Eron, Joseph J Jr ve Group
	b6	]; Sandeep Menon		arah (NIH/NIAID) [E]
	-	change Administrative Grou Recipients/cn=527b1600380	ıp 004a199ae6e0bac2226099-readsa];	Price, Dionne (FDA/CDER)
	•	change Administrative Grou	•	al Dubin Danial D
	•	Recipients/cn=a583eced842 eLabs/ou=Exchange Admini	.c44b18bb6fcd3820bee21-priced.fda strative Group	aj; Rubin, Daniei B.
	•	•	.34111a3ed28f929042aad-RUBIND.f	da]; Farley, John
		eLabs/ou=Exchange Admini Recipients/cn=40b4c4456b1	strative Group 14464788f31fe7bcaa09bc-FARLEYJ.fo	da]; Karen Lvnn Price
	b6	; smith.davey	b6	
	b6	Wohl, David A	<b>b6</b> ; Fischer, William	
		T)/cn=Recipients/cn=f1d19	/NIAID	
	(FYDIBOHF23SPDLT)/cn=l		a74b29bc4cd4f75ef659f5-jroa.s-3.co	]; <b>b6</b> Kim,
		=ExchangeLabs/ou=Exchang Recipients/cn=c48148e4768	e Administrative Group 324ce893260acf33b0f774-kimp2]; li.j	ionathan
	b6 N	larks, Gilbert (OS/ASPR/BAF	RDA) (CTR) [/o=ExchangeLabs/ou=Ex	change Administrative
		T)/cn=Recipients/cn=60008 changeLabs/ou=Exchange /	133606b4f75835d3c77c2eeadb7-Gil Administrative Group	bert.Mar]; Kozak, Marina
			44ad9dc3caa8f497a421-Marina.Koz	a]
CC:	DeMarcus, Forrest		itas, Karen (FNIH) [T] [/o=ExchangeLi ents/cn=40c04fef6f1e46f5b750753c	
			th Kim [elkim@deloitte.com]; Parker	
		change Administrative Grou		, na a ila anna
	(FYDIBOHF235PDLT)/cn=i	; Smith, David	5140faa95aaaafe06ebd70-parkeras] <b>b6</b> ; Paul Klekotka	b6
	Ajay Nirula <b>b6</b>	Elsaid, Olivia [oel	said@deloitte.com]; Robert Jan Ben	!′
Subject:	Re: Confirmed: ACTIV TX-	; Lei Shen <b>b6</b> Clinical mAb Outpatient W1	Meeting-3	
Hi Stacey:				
Tomorrow, I	can make the following	ng times:		
8-9:30 EDT				
10:30-2 EDT				
4:30 onward	s EDT			
Michael				
·····				
	Stacey (FNIH) [T]			

To: LaVange, Lisa M; Michael Hughes; Proschan, Michael (NIH/NIAID) [E]; Eron, Joseph J Jr; currier.judith; Eric Hughes;

APAR0000005313

Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; b6 chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna; b6 kim.peter; Ii.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)  Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E];
roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen <b>Subject:</b> RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3
Hi Lisa,
You are correct. I did have on my to do list for today to get together a meeting of the statistical team for either tonight, tomorrow, or Saturday, according to my notes.
I was going to send a note to the stats group for their availability, but if you all wanted to suggest times for tomorrow that you are available on this thread, I will work to get a meeting scheduled and an invite out.
Thanks, STacey
Stacey J. Adam, PhD Director, Cancer
Research Partnerships Direct: b6   Mobile: b6
From: LaVange, Lisa M b6 Sent: Thursday, May 21, 2020 1:34 PM
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3
Thanks, Michael. I believe it is premature to submit the protocol to your internal review committee. My take-away from yesterday's meeting was that the next step would be for the subgroup of statisticians to meet to discuss the simulations required for the revised trial design. The proposed revisions to the design are needed, in my opinion, to give us the type of flexible, fast-moving master protocol we need to screen a large amount of monoclonal antibodies. But we need to work out some of the design details, so let's have that next meeting as planned. Hoping we can schedule it for some time tomorrow and will work with Stacey to find a time.
From: Michael Hughes b6
Sent: Thursday, May 21, 2020 11:03 AM Subject: Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3
Hi All:
The ACTG team was hoping tomorrow to the NIAID Clinical Science Review
Committee for their review. The protocol design uses standard (widely-used) statistical methods for interim and final analyses but we received the feedback (attached) from ACTIV <b>b5</b>
b5 ), so wanted to respond and get thoughts back as this is a substantial change and would mean that
we would not be able to send for CSRC tomorrow.

I have particular concerns about the need to use the Bayesian paradigm, particularly for Phase III. For a given agent, the Phase 3 study is a fairly simple study involving evaluations for safety, clinical symptoms, and the primary outcome measure of hospitalization/death. We proposed to use standard group sequential monitoring methods which are flexible (using the Lan-DeMets approach for flexible timing of interim analyses with an O'Brien and Fleming type stopping guideline). I think the seamless phase II to phase 3 aspect of the design can be incorporated into this flexible approach by just considering the "look" at the data at the end of phase II as one "look" at the phase 3 primary outcome. This provides protection for the Type I error rate for each specific agent. We can overlay a the possibility of a simple futility rule, eg at >=50% enrollment, to allow stopping for lack of effect (can be justified using a Type II spending boundary, conditional power, or even a Bayesian type rule).

I think this is all quite straightforward. I worry that putting the Phase 3 trial into the Bayesian paradigm gains very little but adds complexity in terms of having to confirm that any Bayesian decision rule does protect Type I error rate for regulatory purposes, and in terms of explaining to many different companies and ultimately to a broad audience. In addition, if the study does go global, it increases the complexity of explaining to IRBs and other review groups.

I would prefer to leave Phase 3 using standard (widely used) statistical methods. I would also favor using standard methods for analysis of Phase 2 data but do agree that Bayesian analyses might also be used for the main efficacy outcome measures to provide an additional perspective in decision-making --- though the main graduation rules (eg observing an absolute 20% reduction in % positive for SARS-CoV-2 at an measurement time, and/or a 20% reduction in mean symptom duration) are straightforward and well-powered.

I would welcome feedback.

Many thanks, Michael

From: Proschan, Michael (NIH/NIAID) [E]	b6				
<b>Sent:</b> Thursday, May 21, 2020 8:52 AM		•			
To: LaVange, Lisa M; Eron, Joseph J Jr; Ada	ım, Stacey (FNIH) [T]; curri	er.judith; Eric Hughes; Sandeep Menon; read.sarah;			
Price, Dionne (FDA/CDER); Rubin, Daniel B	. (FDA/CDER); Farley, John	(FDA/CDER); Karen Lynn Price; smith.davey;			
		scher, William A. II; javan.arzhang; Roa, Jhoanna;			
<b>b6</b> ; kim.peter; li.jonathan; N	Varks, Gilbert (OS/ASPR/B.	ARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)			
Cc: DeMarcus, Forrest; Tountas, Karen (FN	IIH) [T]; Wachtel, Jonathan	; Elizabeth Kim; Parker, Ashley (NIH/OD) [E];			
roa.jhoanna; Smith, David; Paul Klekotka; A	Ajay Nirula; Elsaid, Olivia; I	Robert Jan Benschop; Lei Shen			
Subject: RE: Confirmed: ACTIV TX-Clinical r	mAb Outpatient WT Meeti	ng-3			
I think the question is b5					
<b>b5</b>					

Mike.

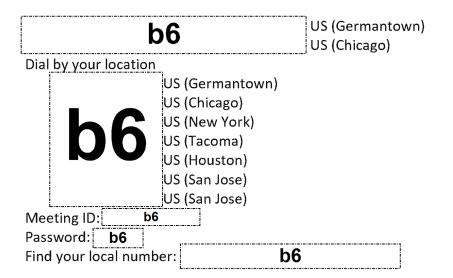
From: LaVange, Lisa M	b6			
Sent: Thursday, May 21		·	,	
To: Eron, Joseph J Jr	b6	, Adam, Stacey (FN		; Judy Currier
b6	Eric Hughes		; Sandeep Menon	
b6	h. Dracahan N	Alabaal (NIIIII (NII A IT) [E]	b6	; Read, Sarah
(NIH/NIAID) [E] (FDA/CDER) ∢	Price,	Dionne (FDA/CDER)	b6	Rubin, Daniel B.
(FDA/CDER) <	<b>b6</b> }; Farle	y, John (FDA/CDER	b6	Karen Lynn Price
	WEAR)	D6		<u>j</u>
b6	Wohl, David A	b6	}; Fischer, William A. II	[
b6	Javan, Arzha ; Kim, Peter (NIH/NIA	ng (NIH/NIAID) [E]	b6 };	Roa, Jhoanna <b>b6</b>
b6	; Kim, Peter (NIH/NIA	ID) [E]; b6		
Marks, Gilbert (OS/ASPI	R/BARDA) (CTR) [	<b>b6</b> Ko	zak, Marina (OS/ASPR/	BARDA)
b6	<u>i</u>		h.c.	
Cc: DeMarcus, Forrest	b6	Lountas, Karen (F	NIH) [1]   D6	, Wachtel, Jonathan
<jwachtel@deloitte.con Jhoanna Roa √</jwachtel@deloitte.con 	n>; Elizabeth Kim <elkin< td=""><td>n@deloitte.com&gt;; Park</td><td>er, Ashley (NIH/OD) [E]</td><td>b6 ;</td></elkin<>	n@deloitte.com>; Park	er, Ashley (NIH/OD) [E]	b6 ;
Jhoanna Roa ∢	<b>b6</b> ; Sm	nith, David <	Pau	il Klekotka
<b>b6</b> Benschop	; Ajay Nirula {	b6 ; Elsaid	d, Olivia < <u>oelsaid@deld</u> 	oitte.com>; Robert Jan
Benschop	b6 ; Lei Sh	nen {b6		
Subject: RE: Confirmed:	ACTIV TX-Clinical mAb	Outpatient WT Meeting	g-3	
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This seems reasonable t			b5	<u></u>
,,,	b5		<u>i</u>	
Lisa				
From: Eron, Joseph J Jr				
Sent: Wednesday, May	20, 2020 6:23 PM	p=====================================		
To: Adam, Stacey (FNIH)	) [T] <b>b6</b> >	; Judy Currier	<b>b6</b> ;	Eric Hughes
b6	; LaVange, Lisa M	b6	Sandeep Menon	
[ b6 (NIH/NIAID) [E] ﴿ (FDA/CDER)	>; Proschan, N	/lichael (NIH/NIAID) [E]	b6	Read, Sarah
(NIH/NIAID) [E] ₹	b6 Price,	Dionne (FDA/CDER)	b6	; Rubin, Daniel B.
(FDA/CDER)	b6 ⟩; Farle	y, John (FDA/CDER)[	b6	Karen Lynn Price
		b6		
b6	Wohl, David A		Fischer, William A. II	
b6	; Javan, Arzha	ng (NIH/NIAID) [E]	b6 };	Roa, Jhoanna <b>b6</b>
b6	Kim, Peter (NIH/NIA	ID) [E] <u>b6</u>	; Jonathan Li	b6
Marks, Gilbert (OS/ASPI	R/BARDA) (CTR) {	<b>b6</b> ; Ko:	zak, Marina (OS/ASPR/	BARDA)
b6	·			
Cc: DeMarcus, Forrest		Tountas, Karen (F		Wachtel, Jonathan
<jwachtel@deloitte.com< td=""><td></td><td></td><td>er, Ashley (NIH/OD) [E]</td><td><b>b6</b> ;</td></jwachtel@deloitte.com<>			er, Ashley (NIH/OD) [E]	<b>b6</b> ;
Jhoanna Roa		nith, David {		Il Klekotka
b6	; Ajay Nirula {	<b>b6</b> >; Elsaid	d, Olivia < <u>oelsaid@del</u> d	oitte.com>; Robert Jan
Benschor	<b>b6</b> →; Lei Sł	nen <b>&lt; b6</b>		
Subject: RE: Confirmed:	ACTIV TX-Clinical mAb	Outpatient WT Meeting	g-3	
Here is my question for	the group – especially f	Vichael, John and Lisa		
My question		b5		
		h <b>E</b>		f
		b5		
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1		~ ~		

## **b**5

Joe Eron MD
Professor of Medicine
University of North Carolina at Chapel Hill
School of Medicine

b6

From: Adam, Stacey (Fl		<b>b6</b>			
<b>Sent:</b> Wednesday, May <b>To:</b> Judy Currier	b6	; Eric Hughes	b6	LaVang	e, Lisa M
b6	Sandeep Men			oschan, Michael	
b6		<b>'</b>	b6	•	, , ,
b6		aniel B. (FDA/CDER) ₹	b6	4	•
b6	; Karen Lynn		b6		]
		b6		; Wohl, David	.i.
b6	Fischer, \	William A. II	b6	Fron, Josepl	
b6	:	rzhang (NIH/NIAID) [E]		; Roa, Jh	(
b6	UNUNUNU	NIH/NIAID) [E]		nathan Li	
Marks, Gilbert (OS/ASP		L		a (OS/ASPR/BARD	PA)
b6		L		• • •	•
Cc: DeMarcus, Forrest	b6	Tountas,	Karen (FNIH) [T]	b6	 }; Wachtel, Jonathar
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b6	>; Paul Kle	kotka b6	; Ajay N		6 Elsaid,
Olivia < oelsaid@deloitt	te.com>; Robert	Jan Benschop <u>{</u>	b6	Lei Shen	b6
Subject: RE: Confirmed	: ACTIV TX-Clinic	al mAb Outpatient WT	Meeting-3	L	
The FDA team that has to offer the attached the Also, attaching again the Thanks, Stacey	noughts for the g	roup's consideration o	n tonight's call.	-	
Stacey J. Adam, PhD Director, Cancer Research Partnerships Direct: b6	Mobile:	b6			
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From:	Michael Hughes b6
Sent:	5/21/2020 5:54:02 PM
То:	LaVange, Lisa M b6 Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham];
	Eron, Joseph J Jr   <b>b6</b> ; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy
	Currier [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-iscurrier.m]; Eric Hughes
	b6 ; Sandeep Menon b6 ; Read, Sarah (NIH/NIAID) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER)
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B.
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price
	b6 smith.davey b6
	<b>b6</b> ; Wohl, David A <b>b6</b> ; Fischer, William A. II
	b6 ; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; <b>b6</b> Kim,
	Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; li.jonathan
	b6 ; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Kozak, Marina
	(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC:	DeMarcus, Forrest b6 ; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
<b>CC</b> .	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh];
	Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; roa.jhoanna
	b6 Smith, David b6 Paul Klekotka b6
	, Smith, David
	Aiav Nirula b6 Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschop  b6 b6 b6  lei Shen b6
Continue	Let Siter .
Subject:	Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3
Hi Lisa,	
That's fine	Perhaps you and Karen could circulate some brief details of the Bayesian model framework and
	· ·
_	priors for each outcome measure you are envisaging? I think that would help in moving things
along.	
Looking for	ward to discussing,
2008	
n a: 1 1	
Michael	
From: LaVan	ge, Lisa M <b>b6</b>
Jent. mursa	ay, May 21, 2020 1:34 PM

To: Michael Hughes; Proschan, Michael (NIH/NIAID) [E]; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; smith.davey; edaar@lundquist.org; chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna; b6 kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)

Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen

Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks, Michael. I believe it is premature to submit the protocol to your internal review committee. My take-away from yesterday's meeting was that the next step would be for the subgroup of statisticians to meet to discuss the simulations required for the revised trial design. The proposed revisions to the design are needed, in my opinion, to give us the type of flexible, fast-moving master protocol we need to screen a large amount of monoclonal antibodies. But we need to work out some of the design details, so let's have that next meeting as planned. Hoping we can schedule it for some time tomorrow and will work with Stacey to find a time.

From: Michael Hughes	b6				
Sent: Thursday, May 21, 2	2020 11:03 AM				
To: Proschan, Michael (NI	H/NIAID) [E]	b6	; LaVange, Lisa M	b6	; Eron,
Joseph J Jr ₹	<b>b6</b> } A	dam, Stacey (FNIF	) [T] 66	; currier.judith	
b6	; Eric Hughes	b6	; Sandeep N	Menon	
b6	; read.sara	ah <b>b6</b>	; Price, Dionn	e (FDA/CDER)	
b6	; Rubin, Daniel	B. (FDA/CDER)	; Price, Dionn	; Farley, John (F	DA/CDER)
b6	Karen Lynn Price	b6	smith.d	lavey b6	
	b6	;	Wohl, David A ∤	b6	; Fischer,
William A. II	b6	javan.arzhang	b6	Roa, Jhoanna	<b>b6</b> ;
<b>b6</b> h; kim.pe	ter < p 6	>; li.jonatha	ın b6	Marks, Gilber	t
(OS/ASPR/BARDA) (CTR)	<b>b6</b>	; Kozak, Ma	arina (OS/ASPR/BARDA	h) <b>b6</b>	
Cc: DeMarcus, Forres	b6	; Tountas,	Karen (FNIH) [T] {	<b>b6</b> ⊳; W	achtel, Jonathan
<jwachtel@deloitte.com></jwachtel@deloitte.com>	; Elizabeth Kim <el< td=""><td>kim@deloitt<u>e.con</u></td><td>n&gt;; Parker, Ashley (NIH</td><td><u>/O</u>D) [E]</td><td>b5</td></el<>	kim@deloitt <u>e.con</u>	n>; Parker, Ashley (NIH	<u>/O</u> D) [E]	b5
roa.jhoanna	<b>b6</b> S	mith, David	b6	^l Paul Klekotka	
b6	>; Ajay Nirula	b6	اً ; Elsaid, Olivia <oelsa< td=""><td>id@deloitte.com&gt;</td><td>; Robert Jan</td></oelsa<>	id@deloitte.com>	; Robert Jan
Benschop <b>b</b> (	6 ; Le	i Shen {	6		
Subject: Re: Confirmed: A	CTIV TX-Clinical m	Ab Outpatient WT	Meeting-3		

## Hi All:

The ACTG team was hoping to submit the A5401 protocol tomorrow to the NIAID Clinical Science Review Committee for their review. The protocol design uses standard (widely-used) statistical methods for interim and final analyses but we received the feedback (attached) from ACTIV about moving to fully use Bayesian methods, so wanted to respond and get thoughts back as this is a substantial change --- and would mean that we would not be able to send for CSRC tomorrow.

I have particular concerns about the need to use the Bayesian paradigm, particularly for Phase III. For a given agent, the Phase 3 study is a fairly simple study involving evaluations for safety, clinical symptoms, and the primary outcome measure of hospitalization/death. We proposed to use standard group sequential monitoring methods which are flexible (using the Lan-DeMets approach for flexible timing of interim analyses with an O'Brien and Fleming type stopping guideline). I think the seamless phase II to phase 3 aspect of the design can be incorporated into this flexible approach by just considering the "look" at the data at the end of

phase II as one "look" at the phase 3 primary outcome. This provides protection for the Type I error rate for each specific agent. We can overlay a the possibility of a simple futility rule, eg at >=50% enrollment, to allow stopping for lack of effect (can be justified using a Type II spending boundary, conditional power, or even a Bayesian type rule).

I think this is all quite straightforward. I worry that putting the Phase 3 trial into the Bayesian paradigm gains very little but adds complexity in terms of having to confirm that any Bayesian decision rule does protect Type I error rate for regulatory purposes, and in terms of explaining to many different companies and ultimately to a broad audience. In addition, if the study does go global, it increases the complexity of explaining to IRBs and other review groups.

I would prefer to leave Phase 3 using standard (widely used) statistical methods. I would also favor using standard methods for analysis of Phase 2 data but do agree that Bayesian analyses might also be used for the main efficacy outcome measures to provide an additional perspective in decision-making --- though the main graduation rules (eg observing an absolute 20% reduction in % positive for SARS-CoV-2 at an measurement time, and/or a 20% reduction in mean symptom duration) are straightforward and well-powered.

I would welcome feedback.

Many thanks, Michael

From: Proschan, N	Лichael (NIH,	/NIAID) [E]	b5			
Sent: Thursday, M	lay 21, 2020	8:52 AM				
To: LaVange, Lisa	M; Eron, Jos	eph J Jr; Adam,	Stacey (FNIH) [T]; cur	rier.judith;	Eric Hughes; Sa	ndeep Menon; read.sarah;
Price, Dionne (FDA	A/CDER); Rul	oin, Daniel B. (Fl	DA/CDER); Farley, Joh	n (FDA/CDE	R); Karen Lynn	Price; smith.davey;
Michael Hughes; b5 chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna;						
b5	kim.peter; l	i.jonathan; Mar	ks, Gilbert (OS/ASPR/	BARDA) (CT	R); Kozak, Mar	ina (OS/ASPR/BARDA)
Cc: DeMarcus, For	rest; Tounta	s, Karen (FNIH)	[T]; Wachtel, Jonatha	n; Elizabeth	n Kim; Parker, A	shley (NIH/OD) [E];
roa.jhoanna; Smit	h, David; Paւ	ul Klekotka; Ajay	/ Nirula; Elsaid, Olivia	; Robert Jan	Benschop; Lei	Shen
Subject: RE: Confi	rmed: ACTIV	TX-Clinical mAl	o Outpatient WT Mee	ting-3		
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Mike.			····			
From: LaVange, Li	sa M	b6				
Sent: Thursday, M	lay 21, 2020			·		
To: Eron, Joseph J	Jr (		>; Adam, Stacey	(FNIH) [T] ፟	b6	Judy Currier
b6		; Eric Hughes	b6	; Sanc	leep Menon	
b6		; Proschan,	Michael (NIH/NIAID)	[E]	b6	>; Read, Sarah
(NIH/NIAID) [E]	b6	>; Price	e, Dionne (FDA/CDER		b6	; Rubin, Daniel B.
(FDA/CDER)	b6	; Farl	ey, John (FDA/CDER)	Immunumunumunumunumunumunumunumunumunumu	b6	Karen Lynn Price

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<jwachtel@deloitte.com< th=""><th>&gt;: Flizabeth Kim</th><th><elkim@deloitte.co< th=""><th>om&gt;: Parker. As</th><th>hlev (NIH/OI</th><th>D) [F]   b6</th><th></th></elkim@deloitte.co<></th></jwachtel@deloitte.com<>	>: Flizabeth Kim	<elkim@deloitte.co< th=""><th>om&gt;: Parker. As</th><th>hlev (NIH/OI</th><th>D) [F]   b6</th><th></th></elkim@deloitte.co<>	om>: Parker. As	hlev (NIH/OI	D) [F]   b6	
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Benschop t	56	: Lei Shen	b6	100100100	, 40101111111111111111111111111111111111	or court
Subject: RE: Confirmed: A	ACTIV TX-Clinica	I mAb Outpatient W	VT Meeting-3			
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Lisa						
From: Eron, Joseph J Jr						
Sent: Wednesday, May 2	0. 2020 6:23 PN	Λ				
To: Adam, Stacey (FNIH)			r 4	b6	Eric Hughes	
b6	LaVange	lisa M b6	: Sai	ndeen Meno	n	
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7		Price, Dionne (FDA				
·	b6	; Farley, John (FDA)	CDFR)		>; Karen Lynn	
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<pre><jwachtel@deloitte.com< pre=""></jwachtel@deloitte.com<></pre>						
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Subject: RE: Confirmed: A		.t ! • • • • • • • • • • • • • • • • • •				
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Joe Eron MD
Professor of Medicine
University of North Carolina at Chapel Hill
School of Medicine

From: Adam, Stacey (							
Sent: Wednesday, Ma	ay 20, 2020 5:42 PM <b>b6</b>	Eria Urrahad		b6	1.01/0	ao lice M	1
To: Judy Currier L	; Sandeep Menon	Eric Hughes			; Lavan chan, Michae	ige, Lisa M L(NIH/NIA	
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<jwachtel@deloitte.c< td=""><td><u>om</u>&gt;; Elizabeth Kim &lt;</td><td>elkim@deloitte.co</td><td><u>m</u>&gt;; Parker,</td><td>Ashley (N</td><td>IH/OD) [E]</td><td>k</td><td>6</td></jwachtel@deloitte.c<>	<u>om</u> >; Elizabeth Kim <	elkim@deloitte.co	<u>m</u> >; Parker,	Ashley (N	IH/OD) [E]	k	6
Jhoanna Roa	b6	Eron, Joseph J Jr		b6		ith, David	
b6	; Paul Klekot			🛚 Ajay Niru	la ﴿	b6	Elsaid,
Olivia < oelsaid@delo	<u>itte.com</u> >; Robert Jan	Benschop	b6		] Lei Shen {	b(	3
Subject: RE: Confirme	ed: ACTIV TX-Clinical r	mAb Outpatient W	T Meeting-3	3			
The FDA team that hat to offer the attached  Also, attaching again  Thanks, Stacey  Stacey J. Adam, Ph Director, Cancer Research Partnershir Direct: b6	thoughts for the grouthe updated synopsis	up's consideration	on tonight's	s call.		-	
Join Zoom Meeting		b6					
Meeting ID:	<b>06</b>						
Password b6	<u>, , , , , , , , , , , , , , , , , , , </u>						
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	US (Tacoma)						
i	US (Houston)						

D6 US (San Jose)
US (San Jose)
Meeting ID b6
Password b6
Find your local number b6

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/21/2020 7:05:20 PM Sent: To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, ; Eisner, Ma<u>rk</u> **b6** Ruxandra | ____; Gottesdiener, Keith Hughes, Eric b6 ; Judy Currier b6 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa **b6** ; Levy, Elliot **b6** ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep 5; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish b6 ]; Peppercorn, Amanda b6 ; Poole, Mike b6 ; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn b6 Garner, Carl b6 ; Higgs, Elizabeth (NIH/NIAID) [E]

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b6 Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy ; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [/o=ExchangeLabs/ou=Exchange Administrative Group

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Optional Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas Attendees: (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; ; Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] b6 ; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Hoots, W. Keith (NIH/NHLBI) [E]; Mensah, George (NIH/NHLBI) [E]; Kiley, James (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E] Dear TX-Clinical WG, Please find attached the slides for the meeting today. We will have some slight updates on the mAb criteria to discuss, but otherwise these are what we will use to review. Thanks, Stacey Join Zoom Meeting **b6** Meeting ID: b6 Password: One tap mobile US (Chicago) **b6** US (New York) Dial by your location US (Chicago) US (New York) US (Germantown) US (San Jose) US (Tacoma) US (Houston) US (San Jose) Meeting ID:

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] 5/21/2020 9:09:35 PM Sent: To: Bascles, Lionel b6 ij; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry ; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy ; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang] CC: Wachtel, Jonathan [jwachtel@deloitte.com]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis];
Hughes, Eric b6 ; Jansen, Kathrin b6 ; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John b6 ; Hamilton, Nancy ; Criffield, Robin ]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group b6 (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth ; Mueller-Reichenstein, Petra ]; Pico, Dianna (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora ; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana ; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; b6 James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, **b6** ; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

Subject:
Summary and action items - CT Capacity WG meeting #10

Attachments: Clinical_Trial_Capacity_Working_Group_Meeting_10_Final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #10 (May 15, 2020) of the full working group. The next full working group meeting is scheduled for Friday, May 22 at 9 am eastern time USA.

Thanks! Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health
b6 | I fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



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Sent: 5/21/2020 9:58:09 PM To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel] Subject: RE: Slides for ACTIV TX-Clinical Working Group Meeting #7 Yes and yes. Let's just do a Skype call. From: Gadbois, Ellen (NIH/OD) [E] b6 Sent: Thursday, May 21, 2020 5:55 PM To: Culp, Michelle (NIH/OD) [E] Subject: RE: Slides for ACTIV TX-Clinical Working Group Meeting #7 Can we chat around 8:30 tomorrow a.m.? And I think we should send LT some kind of short alert tomorrow afternoon about some directives that may not be met cause ICs are doing their own thing anyway, unless they want to intervene with a strong directive. Personally I think this partnership should readjust to go wherever it looks like it can be most helpful and try not to bring sailed ships back, but I tend to be pessimistic about success of central control. From: Culp, Michelle (NIH/OD) [E] b6 Sent: Thursday, May 21, 2020 4:24 PM To: Gadbois, Ellen (NIH/OD) [E] b6 Subject: RE: Slides for ACTIV TX-Clinical Working Group Meeting #7 No, so thanks for sending. I will request Stacey and Mike to add me to the Therapeutics Clinical and Vaccine WG calls. Do you want to chat this evening or tomorrow morning? From: Gadbois, Ellen (NIH/OD) [E] b6 Sent: Thursday, May 21, 2020 4:01 PM b6 To: Culp, Michelle (NIH/OD) [E] Subject: FW: Slides for ACTIV TX-Clinical Working Group Meeting #7 Did you get this in time to join today? I did. You should try to follow this group. They mostly talked about their plans for a master protocol for the mAbs and I'm sure you would get more out of the details. But I have some observations (not urgent to discuss). From: Adam, Stacey (FNIH) [T] Sent: Thursday, May 21, 2020 12:44 PM To: Bozzette, Sam (NIH/NCATS) [E] b6 ; Butterton, Joan b6 ; De Claro, R. Angelo (FDA/CDER) Draghia-Akli, Ruxandra ; Eisner, Mark b6 ; Hughes, Eric Gottesdiener, Keith b6 ; Judy Currier [ Kim, Elizabeth < b6 Levy, Elliot Mellors, John W LaVange, Lisa b6 b6 i; Menon, b6 Sandeep Parker, Ashley (NIH/OD) [E] ; Patel, Naimish Peppercorn, Amanda ; Poole, Mike >; Proschan, Michael (NIH/NIAID) [E] b6 >; Read, Sarah b6 (NIH/NIAID) [E] ; Santos, Michael (FNIH) [T] : Shen, Yuan Li (FDA/CDER) b₆ Stein, Peter (FDA/CDER) b6 Wholley, David (FNIH) [T] Buchman, Tim (OS/ASPR/BARDA) (CTR) b6 ; Collins, Sylva (FDA/CDER) b6 b6 b6 ; Amanda Peppercorn Garner, Carl

Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]

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<b>b6</b> ; Higgs, Elizabeth (NIH/NIAID) [E] <b>b6</b> ; Koroshetz, Walt	ter (NIH/NINDS)
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b6 Aggarwal, Neil (NIH/NHLBI) [E] b6 Rosenberg, Yves (NIH	H/NHLBI) [E]
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b6 ; James, Stephanie (FNIH) [T] b6 ; Wachtel, Jonathan < <u>iwachtel@</u> Tolman, Brett < <u>btolman@deloitte.com</u> >; Alvarez, Rosa < <u>rosalvarez@deloitte.com</u> >; Gonzalez, Nina	defortte.com/,
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<b>b6</b> >; Rubin, Daniel B. (FDA/CDER) <b>b6</b>	,
Subject: Slides for ACTIV TX-Clinical Working Group Meeting #7	
Dear ACTIV TX-Clinical WG,	
Looking forward to seeing you all soon at the meeting. Please find attached the slides for the meeting.	
Thanks,	
Stacey	
Stacey J. Adam, PhD	
Director, Cancer	
Research Partnerships	
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	Jintanat Ananworanich <b>b6</b>
Subject:	ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments:	Clinical Trial Capacity Working Group Meeting Agenda_05222020.pdf; ACTIV Protocol Tracker 05212020.pdf
Location:	b6
Start:	5/22/2020 1:00:00 PM
End:	5/22/2020 1:00:00 PM
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Show Time As:	rentative
Recurrence:	Weekly
	every Tuesday and Friday from 9:00 AM to 10:00 AM
Required	Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C];
Attendees:	Doroshow, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker,
	Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel,
	Jonathan; Qashu, Felicia
Optional	Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gail (NIH/NHLBI) [E]; Mensah, George (NIH/NHLBI) [E]
Attendees:	Garner, Carlos; Denny, Joshua (NIH/OD) [E]; Reid, Nancy (NIH/OD) [C]; Gebo, Kelly (NIH/OD) [G]; Moschetti, Justin
	(NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Hughes,
	Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T];
	Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] <b>b6</b> ; Francis Collins; Gonzalez,
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	Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E]
	b6 Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues, Attached is the Agenda. Please note that we will be hearing from the <u>All of Us</u> program and how they might be useful for implementing ACTIV protocols. In addition, per a request from Tuesday's meeting, attached is the ACTIV Protocol Quick Reference Tracker – thanks to Jonathan and his colleagues for creating this! At present there are three ACTIV protocols, all in the treatment category. CTC Recommendations Committees have been established for the ACTIV-1 and ACTIV-2 protocols to-date and integration with the protocol development and lead network operations teams will take place in the very near future. Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

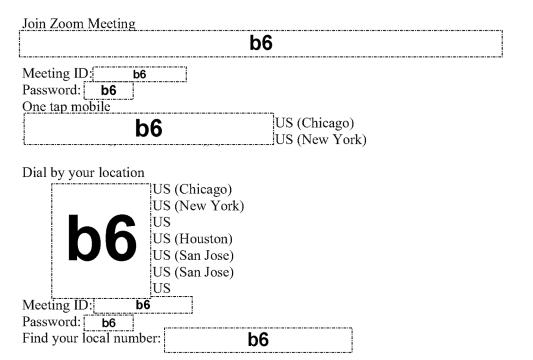
Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards, Karen

Karen H. Tountas, PhD Scientific Program Manager Foundation for the National Institutes of Health



From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] 5/21/2020 10:23:31 PM Sent: b6 ; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group To: Bascles, Lionel (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry **b6** ; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy ; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos ; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura b6 ; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike i]; Wachtel, Jonathan [jwachtel@deloitte.com]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric ; Jansen, Kathrin ; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John ; Criffield, Robin b6 ; Hamilton, Nancy Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth b6 ]; Mueller-Reichenstein, Petra [ (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group b6 ; Pico, Dianna (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana ; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; ; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Heaton, Penny b6 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, j; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

Dear Colleagues,

Attached is the Agenda for the next Clinical Trial Capacity WG meeting, scheduled for tomorrow, Friday May 22, at 9 am eastern US time. Please note that we will be hearing from the <u>All of Us</u> program and how they might be useful for implementing ACTIV protocols.

In addition, per a request from Tuesday's meeting, attached is the ACTIV Protocol Quick Reference Tracker – thanks to Jonathan and his colleagues for creating this! At present there are three ACTIV protocols, all in the treatment category. CTC Recommendations Committees have been established for the ACTIV-1 and ACTIV-2 protocols to-date and integration with the protocol development and lead network operations teams will take place in the very near future.

Best regards, Karen

Karen H. Tountas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

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	[bstratton@DELOITTE.com]; Tolman, Brett [btolman@deloitte.com]; Victoria Davey [/o=ExchangeLabs/ou=Exchange			
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da];			
	Jintanat Ananworanich b6			
Subject:	ACTIV Clinical Trial Capacity Working Group - reporting meeting			
Attachments:	Clinical Trial Capacity Working Group Meeting Agenda_05222020.pdf; ACTIV Protocol Tracker 05212020.pdf			
Location:	b6			
Location.	DO			
Start:	5/22/2020 1:00:00 PM			
End:	5/22/2020 2:00:00 PM			
Show Time As:	rentative			
Recurrence:	Weekly			
	every Tuesday and Friday from 9:00 AM to 10:00 AM			
Required	Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C];			
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Attenuees.	Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel,			
	Jonathan; Qashu, Felicia			
Ontional				
Optional	Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gail (NIH/NHLBI) [E]; Mensah, George (NIH/NHLBI) [E]			
Attendees:	Garner, Carlos; Denny, Joshua (NIH/OD) [E]; Reid, Nancy (NIH/OD) [C]; Gebo, Kelly (NIH/OD) [G]; Moschetti, Justin			
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	Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] <b>b6</b> Francis Collins; Gonzalez,			
	Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuvesson,			
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ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but

understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards, Karen

Karen H. Tountas, PhD Scientific Program Manager Foundation for the National Institutes of Health

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	b6 ; Wachtel, Jonathan [jwachtel@deloitte.com]; Qashu, Felicia (NIH/OD) [E]			
	b6 Vincent, Mike b6			
CC:	Colvis, Christine (NIH/NCATS) [E] b6 ; Jansen, Kathrin b6 ; Lowy,			
	Douglas (NCI) <b>b6</b> Read, Sarah (NIH/NIAID) [E] <b>b6</b> Young, John			
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	[ningonzalez@deloitte.com]; Heaton, Penny b6 James, Stephanie (FNIH) [T]			
	b6 Li, Rose b6 ј; Menetski, Joseph (FNIH) [Т] b6 ;			
'	Santos, Michael (FNIH) [T] b6 Tuvesson, Nancy b6 ; Wholley,			
	David (FNIH) [T] b6 ; Criffield, Robin [robin_criffield@med.unc.edu]; Minnich, Beth			
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	[G] <b>b6</b> Moschetti, Justin (NIH/OD) [E] b6 ; Culp, Michelle (NIH/OD) [E]			
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	<u> </u>			
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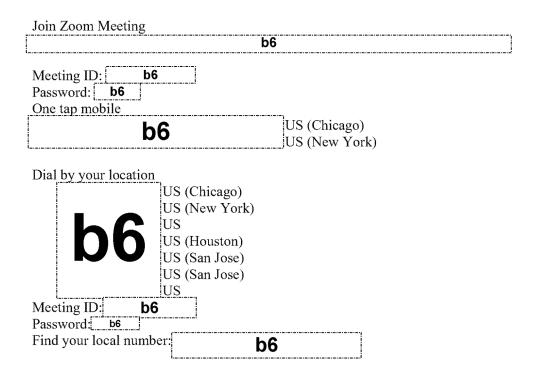
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Karen H. Tountas, PhD Scientific Program Manager Foundation for the National Institutes of Health



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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP					
Cont	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/21/2020 11:37:18 PM					
Sent: To:	Eric Hughes <b>b6</b> ; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange					
10.	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa];					
	Ruxandra Draghia-Akli b6 ; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative					
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel <b>b6</b> ; Colvis,					
	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group					
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John					
	b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group					
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike					
	b6 Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange					
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];					
	Vincent, Michael b6 Keith Gottesdiener b6 Elliott Levy					
	<b>b6</b> ; Wung, Peter /US <b>b6</b> ; Koroshetz, Walter (NIH/NINDS) [E]					
	[/o=ExchangeLabs/ou=Exchange Administrative Group					
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth					
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group					
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner    b6   Goff, David (NIH/NHLBI)   E]   JoeExchangeLabs/ou=Exchange Administrative Group					
	Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]					
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative					
CC.	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa					
	Maria [rosalvarez@deloitte.com]; Salathin, Carla   <b>b6</b>					
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group					
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]					
	[/o=ExchangeLabs/ou=Exchange Administrative Group					
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)					
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group					
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon					
	b6 ]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange					
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];					
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group					
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account					
Subject:	[FNIH@roseliassociates.com] Initial Follow-up to ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12					
Attachments:	ACTIV_Therapeutics-Clinical_Agent Prioritization Subgroup_21May2020_Key Takeaways.pdf					
Attaciments.	ACTIV_Therapeditics-chinical_Agent Filoritization Subgroup_Zitiviay2020_Rey Takeaways.pdi					
Dear TX-Clinio	cal Agent Prioritization Subgroup,					
Dear IX cirri	sar Agent Thornesation Subgroup,					
Please find at	tached the initial follow-up to today's meeting. High level summary and action items are included, as well					
	e members of the sub-teams for review. Please take a look and let me know if you would like to move sub-					
	issigned to one.					
teams of be a	issigned to one.					
Thanks,						
Stacey						
Stacey						
Stanov I Ad	om DAD					
Stacey J. Ad. Director Can						
Director, Cancer Research Partnerships						
Foundation for the National Institutes of Health						
Direct: b6 Mobile: b6						
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	ille Pike, Suite 600, North Bethesda, MD 20852					
A TO A STORY AND A STORY						







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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	5/22/2020 12:00:08 AM
Го:	Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes
	<b>b6</b> ]; LaVange, Lisa M <b>b6</b> ; Sandeep Menon
	b6 ; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham];
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER)
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B.
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price
	b6
	b6 ; Eron, Joe
	<b>b6</b> ]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; <b>b6</b> Kim,
	Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Jonathan Li
	b6 Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Kozak, Marina
	(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC:	Demarcus b6 Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan
	[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa
	<b>b6</b> ]; Eron, Joseph J Jr <u>b6</u> ; Smith, David
	<b>b6</b> Paul Klekotka <b>b6</b> ; Ajay Nirula <b>b6</b> ); Elsaid,
	Olivia [oelsaid@deloitte.com]; Robert Jan Benschop b6 Lei Shen b6;
	Chen, Helen Q. [qingchen@deloitte.com]
Subject:	Notes from the ACTIV TX-Clinical mAb Outpatient WT Meeting-3
Attachments:	ACTIV_Therapeutics-Clinical_ACTIV TX-Clinical mAb Outpatient WT Meeting-3_20May2020_Key Takeaways.pdf;
	Statistical Considerations - Proschan.docx

Dear ACTIV TX-Clinical mAb Outpatient WT,

Please find the notes from last night's writing team meeting for the group's reference. Please note the action items for follow up and the bolded text actions and decisions.

In addition, as requested, I am circulated the document of Statistical Considerations that Mike Proschan put together for ACTIV-1, the large Phase 3.

Thanks, Stacey

Stacey J. Adam, PhD Director, Cancer Research Partnerships Foundation for the National Institutes of Health Direct: b6 | Mobile: b6

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From: Sent:	Eron, Joseph J Jr <b>b6</b> 5/22/2020 1:17:21 AM						
To:	Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier						
	[/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes  b6 ; LaVange, Lisa M b6 ; Sandeep Menon						
	b6 ; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange						
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham];						
	Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group						
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John						
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group						
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	b6						
	b6 Wohl, David A b6 ; Fischer, William A. II						
	b6 ; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative						
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; <b>b6</b> ; Kim,						
	Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Jonathan Li						
	<b>b6</b> Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative						
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Kozak, Marina						
	(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group						
CC:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]  DeMarcus, Forrest [						
CC.	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh];						
	Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]						
	[/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa						
	b6 ]; Smith, David b6 Paul Klekotka b6						
	Ajay Nirula <b>b6</b> Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschop  b6 ; Lei Shen b6 ; Chen, Helen 4: [qingchen@deloitte.com]						
Subject:	RE: Notes from the ACTIV TX-Clinical mAb Outpatient WT Meeting-3						
•	ACTIV_Therapeutics-Clinical_ACTIV TX-Clinical mAb Outpatient WT Meeting-3_20May2020_Key TakeawaysJE.pdf						
	uper informative						
	ary I think there are some decisions that we made – that were supported by the group						
My comment	s are attached in the PDF						
los Eron MD							
Joe Eron MD Professor of N	and in the second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second secon						
	North Carolina at Chapel Hill						
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t							
From: Adam,	Stacey (FNIH) [T] b6						
Sent: Thursda	y, May 21, 2020 8:00 PM						
To: Judy Curri	er <b>b6</b> ; Eric Hughes <b>b6</b> ; LaVange, Lisa M						

b6	Sandeep Menon	b6		; Proschan, M	ichael (NIH	/NIAID)	[E]
b6	Read, Sarah (NIH/NIA	AID) [E]	b6	þ; Price, Di	onne (FDA/	CDER)	
b6	; Rubin, Daniel B. (FD	DA/CDER)	b6	} Fa	ırley, John (	FDA/CE	DER)
b6	; Karen Lynn Price		b6				
	b6			Wohl,	David A		
<b>b</b> 6	; Fischer, William A.	1			, Joseph J Jr		
**************************************	; Javan, Arzhang (N	IH/NIAID) [E]	b6	>;	Roa, Jhoanr	າa i b	6
b6	Kim, Peter (NIH/NIAID	) [E] <b>b</b> (	6	; Jonathan Li	l	b6	
Marks, Gilbert (OS/ASPR)	/BARDA) (CTR)	b6	្រៃ Kozak, Ma	arina (OS/ASPÌ	R/BARDA)		
b6							
Cc: DeMarcus, Forrest <	b6	Tountas, Kar	en (FNIH) [T	] b6	<b>þ</b> ; ۱	<b>Vachte</b>	, Jonath
<jwachtel@deloitte.com< td=""><td>&gt;; Elizabeth Kim <elkim@< td=""><td></td><td></td><td></td><td></td><td></td><td></td></elkim@<></td></jwachtel@deloitte.com<>	>; Elizabeth Kim <elkim@< td=""><td></td><td></td><td></td><td></td><td></td><td></td></elkim@<>						
Jhoanna Roa	<b>b6</b> >; Eron	, Joseph J Jr	b	6	j; Smith, D	avid	
b6	>; Paul Klekotka	b6	j; Aja	y Nirula	b6	ļ	; Elsaid,
Olivia <oelsaid@deloitte.< td=""><td>.com&gt;; Robert Jan Benscl</td><td>hop {</td><td>b6</td><td>; Lei Sh</td><td></td><td>b6</td><td>ļ</td></oelsaid@deloitte.<>	.com>; Robert Jan Benscl	hop {	b6	; Lei Sh		b6	ļ
Chen, Helen Q. ঊ्qingche	n@deloitte.com>				1		
Subject: Notes from the	ACTIV TX-Clinical mAb Ou	utpatient WT Me	eeting-3				

Dear ACTIV TX-Clinical mAb Outpatient WT,

Please find the notes from last night's writing team meeting for the group's reference. Please note the action items for follow up and the bolded text actions and decisions.

In addition, as requested, I am circulated the document of Statistical Considerations that Mike Proschan put together for ACTIV-1, the large Phase 3.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

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	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa];
	Ruxandra Draghia-Akli <b>b6</b> Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel <b>b6</b> ; Colvis,
	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	b6 Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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	b6 Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange
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	<b>b6</b>   Wung, Peter /US <b>b6</b>   Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	b6 ; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
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	Maria [rosalvarez@deloitte.com]; Salathin, Carla
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	[/o=ExchangeLabs/ou=Exchange Administrative Group
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	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account
	[FNIH@roseliassociates.com]; Chen, Helen Q. [qingchen@deloitte.com]
Subject:	ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #13
Location:	b6
Start:	5/28/2020 4:00:00 PM
End: Show Time As:	5/28/2020 5:00:00 PM
Snow Time As:	Tentative
Required	Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine
Attendees:	(NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR);
	Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs,
	Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; b6
Attendees:	Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula
	(NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] b6; Rose Li Central Account; Chen, Helen Q.
~	
Stacey Adam	is inviting you to a scheduled Zoom meeting.
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Sent:	5/22/2020 2:30:59					
Го:		) [T] [/o=ExchangeLabs				
	b6	/cn=Recipients/cn=dc	d875f0679648859e	e1cf101c0943414	-adamsj4]; Ruxa	ındra Draghia-Akli
	b6	; Naimish Patel	b6	Colvis, C	nristine (NIH/NO	CATS) [E]
	[/o=ExchangeLabs/c	ou=Exchange Administ	rative Group			
	(FYDIBOHF23SPDLT)	)/cn=Recipients/cn=4b	7e84cce098457896	5b2df19fa172c87	-ccolvis]; Young	, John
	b6	; Stein, Peter	(FDA/CDER) [/o=E>	changeLabs/ou=	Exchange Admii	nistrative Group
	(FYDIBOHF23SPDLT)	)/cn=Recipients/cn=b4				
	b6		man, Tim (OS/ASPR			
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	(FYDIBURF233PDLI)	)/cn=Recipients/cn=50 e.com]; Salathin, Carla	0131520043427635	b6		
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		)/cn=Recipients/cn=30		35aaaate06ebd70	-parkeras]; Who	olley, David (FNIH) [1]
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	·	)/cn=Recipients/cn=cd		d0b6996d677257	-wholleyd]; Me	encio, Cheryl (FNIH)
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	·	)/cn=Recipients/cn=27			f-melencioc]; W	alker, Paula
		=ExchangeLabs/ou=Exc	_	•		
	·	)/cn=Recipients/cn=fbe		5fd03bcfd32930-	walkerp1]; War	d, Jackie (NIH/NINDS)
		os/ou=Exchange Admir	·			
	(FYDIBOHF23SPDLT)	)/cn=Recipients/cn=41	14c7d13389454f89	9fe3411cb3a834f-	-wardjam]	
Subject:	Canceled: ACTIV TX-	-Clinical Agent Prioritiz	ation- mAb Subtea	m Meeting		
ocation:		b	6			
Start:	5/28/2020 4:00:00 I	PM				
End:	5/28/2020 5:00:00 [					
	e. [ros					

Show Time As: Free

Required Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Amanda Peppercorn; Breuer, Sebastian; Martin, Flavius; Andrew Charles Adams; John Mellors; Marovich, Mary (NIH/NIAID) [E]; Judy Currier; Tressler, Randall (NIH/NIAID) [E]; Smith, David Attendees: Elizabeth Kim; Chen, Helen Q.; Payton, Natalie; Andrew Para; GMM76@pitt.edu; Dana Carluccio; Lucas Smalldon; Optional

Attendees: Rose Li Central Account

Dear ACTIV TX-Clinical Agent Prioritization team,

Thank you all for your responses. We will be converting this meeting into a mAb Subteam meeting for tomorrow in the hope of finalizing the minimal entry criteria.

Thank you all for your flexibility and understanding.

Stacey

Join Zoom Meeting	
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Password: b6	
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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
Country	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: To:	5/22/2020 2:30:59 AM Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
10.	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes
	b6 ]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli
	b6 } Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel <b>b6</b> Colvis, Christine
	(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John
	b6 Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike
	b6 ; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];
	Vincent, Michael b6 Keith Gottesdiener b6 ; Elliott Levy
	b6 ; Wung, Peter /US b6 ; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner
	b6 ; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	Maria [rosalvarez@deloitte.com]; Salathin, Carla <b>b6</b>
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon  b6 ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account
	[FNIH@roseliassociates.com]; Chen, Helen Q. [qingchen@deloitte.com]
Subject:	ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #13
Location:	b6
Start:	5/28/2020 4:00:00 PM
End: Show Time As:	5/28/2020 5:00:00 PM
Show time As:	Tentative
Required	Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine
Attendees:	(NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR);
	Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs,
	Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional	Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; b6
Attendees:	Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula
	(NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] b6 Rose Li Central Account; Chen, Helen Q.
~.	
Stacey Adam	is inviting you to a scheduled Zoom meeting.

APAR0000028276

Join Zoom Meeting b6 b6 Meeting ID: Password: **b6** One tap mobile US (Chicago) **b6** US (New York) Dial by your location US (Chicago) US (New York) US (Germantown) US (San Jose) US (Tacoma) US (Houston) US (San Jose) Meeting ID: Password: **b6** Find your local number: b6

From:	Menon, San	' i	b6					
Sent:	5/22/2020 1			 . N 4: -l   1				
То:	Karen Lynn I		b6 schap Michael	Michael H ;		b6	LaVange, Lisa M	
	b6; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Eron, Joseph J Jr							
	b6 ; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group							
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	(FYDIBOHF2	3SPDLT)/cn=Rec	ipients/cn=527	b160038004a1	.99ae6e0bac2	226099-readsa];	; Price, Dionne (FDA/CDER)	
	[/o=Exchang	eLabs/ou=Excha	ange Administr	ative Group				
		•	•			Obee21-priced.fo	da]; Rubin, Daniel B.	
		[/o=ExchangeLa						
			•			042aad-RUBIND.	.fda]; Farley, John	
		[/o=ExchangeLa						
	(FYDIBOHF2	3SPDLT)/cn=Rec	ipients/cn=40k <b>b6</b>	04c4456b14464	/88f31fe/bca		fda]; smith.davey	
	<u> </u>	he i		Λ II.			ohl, David A	
	[/o=Eychang	<b>b6</b> seLabs/ou=Excha	l; Fischer, Willia	L	b6	j; Java	n, Arzhang (NIH/NIAID) [E]	
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	•	geLabs/ou=Excha			5621333G7aa	132704-javanaro	j, Koa, moanna	
					9bc4cd4f75ef	f659f5-iroa.s-3.c	o]; LHosey@s-3.com; Kim,	
		NIAID) [E] [/o=Ex					on Energy of Steelin, Killing	
			-	_		o0f774-kimp2]; li	.ionathan	
	) b6						Exchange Administrative	
	Group (FYDI						ilbert.Mar]; Kozak, Marina	
	(OS/ASPR/B	ARDA) [/o=Excha	angeLabs/ou=E	xchange Admir	istrative Grou	ıp		
	(FYDIBOHF2	3SPDLT <u>)</u> /cn=Rec	ipients/cn=ff38	881f41df744ad	9dc3caa8f497	a421-Marina.Ko	za]	
CC:	DeMarcus, F		b6				Labs/ou=Exchange	
			• • •				3cd5a14f93-tountaskh];	
					n [elkim@delo	oitte.com]; Parke	er, Ashley (NIH/OD) [E]	
	-	geLabs/ou=Excha	_					
	(FYDIBOHF2			,		ebd70-parkeras ]; Paul Klekotka		
	Aiay Nigula i	b6	Smith, David	L		]; Paul Klekotka: ]; Robert Jan Bei		
	Ajay Nirula	<b>b6</b>	j; Elsalu,	b6	odeloitte.com	j; Kobert Jan ber	теспор	
Subject:	Re: [FXTFRN	AL] Re: Confirm			! natient WT M	eeting-3		
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Thanks Karen	It would be	e tricky to have	e "informative	" nrior incorn	orated as the	e data is still ev	olving. I am assuming we	
							the data evolves. There	
	-			•	•	en endpoints,		
are too many	variables ne	ere – evolving s	oc, reciditin	entrate, corre	nation betwe	en enaponis,	etc	
	;							
From: Karen	i	b6						
Date: Friday	, May 22, 2	020 at 12:07 $\prime$	AM					
To: Michael	Hughes		b6	, "La\	/ange, Lisa ſ	M"	b6	
"Proschan, N	∕lichael (NII	H/NIAID) [E]"[		b6	"Eron, Jo	oseph J Jr"		
I			m, Stacey (FI	VIH) [T]"	b6	, "currier.	iudith"	
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i !	L C		read.sarah"	b6		•	re@fda.hhs.gov"	
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(55.4./55.55)	b6	<del></del>	, Daniel B. (F	·		b6	, "Farley, John	
(FDA/CDER)'	` <u>[</u>	b6	, "smith.	davey"		b6		
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b6	⇒, "Fischer,	William A. II"		o6	, "javan.aı	rzhang"
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"kim.peter" b	6 , "li.j	jonathan"	b6	, "Marks,	Gilbert (OS/A	ASPR/BARDA)
(CTR)" b6	, "Koza	ak, Marina (OS/	ASPR/BARDA)"	b6	<b>&gt;</b>	
Cc: "DeMarcus, Forrest"	" b(	6,	"Tountas, Kare	n (FNIH) [T]"	b6	},
"Wachtel, Jonathan" <j< td=""><td>wachtel@deloitt</td><td>e.com&gt;, Elizab</td><td>eth Kim <elkim< td=""><td>@deloitte.com</td><td>ı&gt;, "Parker, A</td><td>shley</td></elkim<></td></j<>	wachtel@deloitt	e.com>, Elizab	eth Kim <elkim< td=""><td>@deloitte.com</td><td>ı&gt;, "Parker, A</td><td>shley</td></elkim<>	@deloitte.com	ı>, "Parker, A	shley
(NIH/OD) [E]"	b6	"roa.jhoanna'	' []	o <b>6</b>	>, "Smith, D	avid"
b6	, Paul Klel	kotk	b6	, Ajay Nirul	a k	o6
"Elsaid, Olivia" <oelsaid< td=""><td>@deloitte.com&gt;</td><td>, Robert Jan Be</td><td>nschop</td><td>b6</td><td>,</td><td>i Shen</td></oelsaid<>	@deloitte.com>	, Robert Jan Be	nschop	b6	,	i Shen
b6						

Subject: Re: [EXTERNAL] Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks Lisa and Michael.

Working now to put together more details on the modeling and developing a simulation plan. We look forward to discussing in our stats meetings soon. Whether we end up with Bayesian or frequentist approach, simulation of this design will be required in order to better understand the operating characteristics.

I do think it is important we keep in mind that for a master protocol such as this, the specific model used and associated priors will necessarily change over time. So the intent would be to put the basic framework of the model into the master protocol, but specify the model, agent's specific sample size, and operating characteristics assessed via simulation in the associated agent's appendix. One advantage of this is that in order to navigate through these many agents efficiently and effectively we necessarily need to learn over time and formally incorporate that learning into our modeling. For example, we will learn more over time about the relationship between the symptomatic endpoints/viral endpoints/clinical endpoint (hospitalization/er visit/death) and that learning needs to be incorporated into future agent's modeling, which should also lower sample size and improve precision/decision making across these agents. It is presently unclear to me how we can effectively evaluate several agents / borrow placebo / incorporate prior knowledge we will gain over time / etc without a Bayes approach, but I look forward to discussing in our stats meetings.

Thanks, Karen

From: Michael Hughes	b6					
Date: Thursday, May 2:	1, 2020 at 12:54 PN	1				
To: "LaVange, Lisa M" <	lisa.lavange@unc.ه	edu>, "Proschan,	, Michael (NIH	/NIAID) [E]"		
b6	>, "Eron, Joseph	J Jr" ₹	b6	"Adam,	Stacey (FNIH)	[T]"
<b>b6</b> →, "cι	ırrier.judith" [	b6	, Eric I	lughes	b6	
Sandeep Menon	b6	, "read	.sarah"	b6	, "Price, D	ionne
(FDA/CDER)"	b6	"Rubin, Daniel	B. (FDA/CDER	)"[	b6	<del>-</del>
"Farley, John (FDA/CDE	R)" <b>b</b> 6	, Kar	en Price	b6		
,"smith_davev"		b6		>,	"chew.kara"	
b6	, "Wohl, David	A" [	b6	, "Fischer, V	Villiam A. II"	
b6	, "javan.a	rzhang"	b6	, "Roa, Jho	anna"	b6
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	, "Marks, Gilbert (0		) (CTR)"[	b6	"Kozak	, Marina
(OS/ASPR/BARDA)"	b6					
Cc: "DeMarcus, Forrest	' b6	, "Toı	untas, Karen (	FNIH) [T]"	b6	·
"Wachtel, Jonathan" <j< td=""><td>wachtel@deloitte.d</td><td>com&gt;, Elizabeth I</td><td>Kim <elkim@d< td=""><td>leloitte.com&gt;, '</td><td>'Parker, Ashle</td><td>:y</td></elkim@d<></td></j<>	wachtel@deloitte.d	com>, Elizabeth I	Kim <elkim@d< td=""><td>leloitte.com&gt;, '</td><td>'Parker, Ashle</td><td>:y</td></elkim@d<>	leloitte.com>, '	'Parker, Ashle	:y
(NIH/OD) [E]"	<b>b6</b> >, "	roa.jhoanna'	b6	11	Smith, David'	1

b6 , Paul Klekotka "Elsaid, Olivia" <oelsaid@deloitte.com>, Robert Jan Be</oelsaid@deloitte.com>	b6	Ajay Nirula	b6 },
"Elsaid, Olivia" <oelsaid@deloitte.com>, Robert Jan Be</oelsaid@deloitte.com>	nschop	b6	, Lei Shen
b6 >			
Subject: [EXTERNAL] Re: Confirmed: ACTIV TX-Clinical i	mAb Outpa	tient WT Meeting-3	
EXTERNAL EMAIL: Use caution before rep	alvina clic	king links and onenin	n attachmente
m/41 militaram missirasm. Our consort sortice to	orymig, one	and openin	g attachmicities.
Hi Lisa,			
That's fine. Perhaps you and Karen could circulate som	ne brief deta	nils of the Bayesian mod	lel framework and
associated priors for each outcome measure you are env			
along.			
Looking forward to discussing,			
Zeeling fer ward to discussing,			
Michael			
From: LaVange, Lisa M b6 >			
From: LaVange, Lisa M b6  Sent: Thursday, May 21, 2020 1:34 PM			
To: Michael Hughes; Proschan, Michael (NIH/NIAID) [E]; Ero	n, Joseph J J	r; Adam, Stacey (FNIH) [T	]; currier.judith; Eric
Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/C	-		
\		David A; Fischer, William	
Roa, Jhoanna; <b>b6</b> kim.peter; li.jonathan; Ma	rks, Gilbert (	OS/ASPR/BARDA) (CTR); k	Kozak, Marina
(OS/ASPR/BARDA)	lanathan: El	izahath Kimi Darkar Ashli	w (NIH/OD) [E]:
<b>Cc:</b> DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, . roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid			
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient V		• *	

Thanks, Michael. I believe it is premature to submit the protocol to your internal review committee. My takeaway from yesterday's meeting was that the next step would be for the subgroup of statisticians to meet to discuss the simulations required for the revised trial design. The proposed revisions to the design are needed, in my opinion, to give us the type of flexible, fast-moving master protocol we need to screen a large amount of monoclonal antibodies. But we need to work out some of the design details, so let's have that next meeting as planned. Hoping we can schedule it for some time tomorrow and will work with Stacey to find a time.

Lisa

From: Michael Hughes	ş b	6			
G 4 TE1 1 34 0	1 0000 11 00 13 5				
To: Proschan, Michael  b6  b6  cu  Sandeep Menon  (FDA/CDER)  Farley, John (FDA/CD)  smith.davey  David A  b  To: Proschan, Michael  cu  ball  particular  b  ball  particular  b  ball  particular  b  ball  particular  b  ball  particular  particular  b  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  particular  part	(NIH/NIAID) [E] {	b6	⊳; LaVange,	, Lisa M	
<b>b6</b>	Eron, Joseph J Jr	b6	, Adam	ı, Stacey (FNII	H) [T]
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Sandeep Menon	b6	; read.sarah	b6	Price,	Dionne
(FDA/CDER)	b6	; Rubin, Daniel B.	(FDA/CDER) €	b6	
Farley, John (FDA/CD)	ER) <b>b6</b>	; Karen	Lynn Price <	b6	
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b6 	; Roa, Jhoanna	b6	; k	tim.peter	-
b6	; li.jonathan	b6 ; M	arks, Gilbert (OS	/ASPR/BARD	A) (CTR)
∯ <b>b6</b>	; Kozak, Marina	ı (OS/ASPR/BARD <i>A</i>	A)  b6	ļ	
Cc: DeMarcus, Forrest	b6	Tountas, I	Karen (FNIH) [T]	b6	<b>;</b> ;
Wachtel, Jonathan <jwa< td=""><td></td><td></td><td></td><td></td><td></td></jwa<>					
[E] <b>b6</b>			Smith,		
b6	; Paul Klekot	ka <b>b6</b>	>; Ajay	Nirula	
b6	; Elsaid, Olivia <	oelsaid@deloitte.com	n>; Robert Jan Be	nschop	
	; Lei Shen		į	_	
Subject: Re: Confirme	d: ACTIV TX-Clini	ical mAb Outpatient	WT Meeting-3		

## Hi All:

The ACTG team was hoping to submit the A5401 protocol tomorrow to the NIAID Clinical Science Review Committee for their review. The protocol design uses standard (widely-used) statistical methods for interim and final analyses but we received the feedback (attached) from ACTIV about moving to fully use Bayesian methods, so wanted to respond and get thoughts back as this is a substantial change --- and would mean that we would not be able to send for CSRC tomorrow.

I have particular concerns about the need to use the Bayesian paradigm, particularly for Phase III. For a given agent, the Phase 3 study is a fairly simple study involving evaluations for safety, clinical symptoms, and the primary outcome measure of hospitalization/death. We proposed to use standard group sequential monitoring methods which are flexible (using the Lan-DeMets approach for flexible timing of interim analyses with an O'Brien and Fleming type stopping guideline). I think the seamless phase II to phase 3 aspect of the design can be incorporated into this flexible approach by just considering the "look" at the data at the end of phase II as one "look" at the phase 3 primary outcome. This provides protection for the Type I error rate for each specific agent. We can overlay a the possibility of a simple futility rule, eg at >=50% enrollment, to allow stopping for lack of effect (can be justified using a Type II spending boundary, conditional power, or even a Bayesian type rule).

I think this is all quite straightforward. I worry that putting the Phase 3 trial into the Bayesian paradigm gains very little but adds complexity in terms of having to confirm that any Bayesian decision rule does protect Type I error rate for regulatory purposes, and in terms of explaining to many different companies and ultimately to a broad audience. In addition, if the study does go global, it increases the complexity of explaining to IRBs and other review groups.

I would prefer to leave Phase 3 using standard (widely used) statistical methods. I would also favor using standard methods for analysis of Phase 2 data but do agree that Bayesian analyses might also be used for the main efficacy outcome measures to provide an additional perspective in decision-making --- though the main graduation rules (eg observing an absolute 20% reduction in % positive for SARS-CoV-2 at an measurement time, and/or a 20% reduction in mean symptom duration) are straightforward and well-powered.

I would welcome feedback.
Many thanks,
Michael
From: Proschan, Michael (NIH/NIAID) [E] <b>b6</b> Sent: Thursday, May 21, 2020 8:52 AM
<b>To:</b> LaVange, Lisa M; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep
Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER);
Karen Lynn Price; smith.davey; Michael Hughes; b6 ; chew.kara; Wohl, David A; Fischer,
William A. II; javan.arzhang; Roa, Jhoanna; kim.peter; li.jonathan; Marks, Gilbert
(OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)
Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley
(NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop;
Lei Shen
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

APAR0000005292

I think the question is whether we could stop early for efficacy as well as stopping early for futility. That could certainly be incorporated if you think there is a realistic possibility of crossing an efficacy boundary after only 50 people. At the halfway point, the O'Brien-Fleming-like spending function boundary for the z-score is close to 3, so you would have to see a very large z-score to stop that early for efficacy.

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1 V I	1	n.	

From: LaVange, Lisa M	b6					
Sent: Thursday, May 21, 2	020 7:53 AM					
To: Eron, Joseph J Jr Currier b6 b6	b6	; A	dam, Stacey (FN	TH) [T] 🖳	b6	나; Judy
Currier b6	}; Er	ric Hughes	b6		indeep Meno	n
b6	; Pros	chan, Michael	(NIH/NIAID) [E	3	b6	; Read,
Sarah (NIH/NIAID) [E]	b6	; Price	e, Dionne (FDA/	CDER)	b6	>;
Rubin, Daniel B. (FDA/CD	PER)	b6	; Farley, Jo	hn (FDA/CD	ER)	
b6	: Karen Lvnn	Price		b6		
	<del></del>	b6			, Wohl, I	David A
b6 (NIH/NIAID) [E] [ (NIH/NIAID) [E] [ (OS/ASPR/BARDA) (CTR	; Fischer, W	Villiam A. II	b6		; Javan, Aı	rzhang
(NIH/NIAID) [E]	b6	; Roa, Jho	anna	b6		Kim, Peter
(NIH/NIAID) [E]	b6	Jonathan Li	b6	; Ma	rks, Gilbert	
(OS/ASPR/BARDA) (CTR	5) {	b6	; Kozak, Marina	a (OS/ASPR/	BARDA)	
	<u>.i</u>					
Cc: DeMarcus, Forrest	b6	; T	ountas, Karen (F	NIH) [T]	b6	
Wachtel, Jonathan	@deloitte.co	om>; Elizabeth	Kim < elkim@c	leloitte.com>	, Parker, Ash	ley (NIH/OD)
[E] < <b>b6</b>	; Jhoanna R	Roa	b6 <b>b6</b>	<b>&gt;</b> ; Smith, □	avid	
[E] < b6 b6	; Paul Klel		b6	; Ajay Nirı	ıla	
b6   ⊳; ]	Elsaid, Olivia ̈	<oelsaid@dele< td=""><td>oitte.com&gt;; Robe</td><td>ert Jan Bensch</td><td>юр</td><td></td></oelsaid@dele<>	oitte.com>; Robe	ert Jan Bensch	юр	
b6	; Lei Shen		<u> </u>		_	
Subject: RE: Confirmed: A	ACTIV TX-Cl	inical mAb Oı	itpatient WT Me	eting-3		

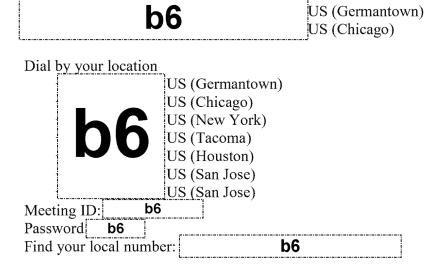
This seems reasonable to me. We can define any basis that we think will be important for dropping dose arms or entire agents, having little to go on at this point in terms of what best predicts hospitalizations.

Lisa

From: Eron, Joseph J Jr					
Sent: Wednesday, May 20					
To: Adam, Stacey (FNIH)	[T] <b>b6</b>	; Judy Curr	ier <b>b</b> 6		; Eric Hughes
b6	; LaVange, Lisa			eep Menon	
b6		ı, Michael (NIH/		b6	>; Read,
Sarah (NIH/NIAID) [E]	b6	; Price, Dion	ne (FDA/CDER)		b6 ;
Rubin, Daniel B. (FDA/CI	DER)[	b6 >;	Farley, John (FDA	/CDER)	
b6	Karen Lynn Pric	ce {	b6		
	b6		7:	; Wo	hl, David A
b6	; Fischer, Willi	am A. II ॑	b6	; Javar	ı, Arzhang
(NIH/NIAID) [E]	b6	; Roa, Jhoanna ₹	b6		Kim, Peter

(NIH/NIAID) [E] <b>b6</b> ; Jonathan Li <b>b6</b> ; Marks, Gilbert						
(OS/ASPR/BARDA) (CTR) b6 >; Kozak, Marina (OS/ASPR/BARDA)						
b6						
Cc: DeMarcus, Forrest b6 >; Tountas, Karen (FNIH) [T] b6 ;						
Wachtel, Jonathan ;; Elizabeth Kim <u>elkim@deloitte.com</u> ; Parker, Ashley (NIH/OL						
[E] <b>b6</b> ; Jhoanna Roa <b>b6</b> ; Smith, David						
b6 ; Paul Klekotka b6 ; Ajay Nirula						
Elsaid, Olivia < oelsaid@deloitte.com >; Robert Jan Benschop						
Selicate DE: Confirmed A CTIVITY Clinical and h Contration AVT Montage 2						
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3						
Here is my question for the group – especially Michael, John and Lisa						
My question is whether there could be an interim "activity" analysis similar to the futility analysis listed below – the reason I ask is we have very little longitudinal data on the quantitative viral shedding and it is possible th this endpoint would have substantial power such that 50 patients per arm could provide an antiviral answer.						
If the Phase 2 portion of the Clinical mAb protocol is used for dose finding, this may be challenging with respect to size of the trial (number of treatment arms needed and available sample size per treatment arm). In addition, it may be appropriate to establish an interim futility analysis based on change in quantitative viral shedding to allow for discontinuation of a dose after e.g. 50 rather than 110 patients, or to allow early discontinuation of high doses due to safety findings.						
Joe Eron MD						
Professor of Medicine						
University of North Carolina at Chapel Hill						
School of Medicine						
<b>b6</b>						
From: Adam, Stacey (FNIH) [T] { b6   Sent: Wednesday, May 20, 2020 5:42 PM						
To: Judy Currier b6 ; Eric Hughes < b6 ; LaVange, Lisa M						
b6						
[E] <b>b6</b> ; Read, Sarah (NIH/NIAID) [E] <b>b6</b> ; Price, Dionne						
(FDA/CDER) b6; Rubin, Daniel B. (FDA/CDER) b6						

Farley, John (FDA/CDF	ER)	b6	; Kare	n Lynn Pric	e[	b6	<u></u> ,
TV-11 D 1 A				A TT !		L C	
Wohl, David A	b6		scher, Willia		rmai	Db LC	>; Eron,
Joseph J Jr	b6		Arzhang (N			<b>b6</b>	; Roa,
Jhoanna L	) Modra		m, Peter (NI	/ •	- ,		Jonathan
Li <b>b6</b> Marina (OS/ASPR/BAF		b6	ASPR/BAR	DA) (CIK)	1	b6	; Kozak,
Cc: DeMarcus, Forrest		)6	Tounte	, Karen (FN	лы) [т]	b6	
Wachtel, Jonathan < jwa	i						
[E] { <b>b6</b>	; Jhoani		b6	CIRIII		oseph J Jr	isincy (Millob)
	>; Smith	l	b6	3	; Paul K		
b6	Ajay Ni		b6	>: Elsa	` `		eloitte.com>;
Robert Jan Benschop	b		; Lei She	·	b6	<u> </u>	,
Subject: RE: Confirme	d: ACTIV TX	-Clinical m	!′	L	ting-3	!	
Dear mAb Outpatient W The FDA team that has would like to offer the a Also, attaching again th Thanks, Stacey	been working ttached thoug	hts for the g	group's cons	deration on	tonight's	call.	•
Stacey J. Adam, PhD							
wearney we charteness x xxx.							
Director, Cancer							
Research Partnerships							
Direct: <b>b6</b>	Mobile:	b6					
Join Zoom Meeting		b6					
Meeting ID: <b>b6</b> Password: <b>b6</b> One tap mobile							



From:	Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=60008133606B4F75835D3C77C2EEADB7-GILBERT.MAR]							
Sent:	5/22/2020 11:45:10 AM							
To:	Karen Lynn Price <b>b6</b> ]; Michael Hughes <b>b6</b> LaVange, Lisa M							
	[lisa.lavange@unc.edu]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Eron, Joseph J Jr							
	b6 ; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	'(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier							
	[/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes							
	<b>b6</b> Sandeep Menon <b>b6</b> ; Read, Sarah (NIH/NIAID) [E]							
	[/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER)							
	[/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B.							
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John							
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; smith.davey							
	b6 ; Wohl, David A							
	b6 ; Fischer, William A. II ( b6 ); Javan, Arzhang (NIH/NIAID) [E]							
	[/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna							
	[/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; b6 Kim,							
	Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; li.jonathan							
	b6 Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]							
CC:	DeMarcus, Forrestb6 Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange							
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh];							
	Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]							
	[/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; roa.jhoanna							
	<b>b6</b> ; Smith, David <b>b6</b> ; Paul Klekotka <b>b6</b> ;							
	Ajay Nirula <b>b6</b> ; Elsaid, Olivia [oelsaid@deloitte.com]; Robert Jan Benschop							
	b6 Lei Shen b6							
Subject:	RE: [EXTERNAL] Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3							

Obviously Regulatory approval is the objective. How comfortable will other sponsors be with anything other than 'traditional' measures for PhIII success? If I'm translating correctly, traditional analyses could be the default yet include Bayesian approaches as prospective ways to explore the data and perhaps evolve to in time as sponsors and regulators become more comfortable with the endpoints, the nature of the data and the alignment of the analyses, and importantly, the ability to clearly, globally communicate the results for each of the raft of compounds being assessed.

From my perspective, sponsors have been concerned about moving to total Bayesian approaches especially in view of where primary endpoints have no clear track record for demonstrating success and with a global registration strategy in mind. One consideration would be to write down mock trial results as would be communicated following a successful trial with, for example, time to event, proportions and Bayesian approaches. The strengths and weaknesses behind each (sample size, other) may help a range of sponsors, IRBs, investigators and regulatory agencies more quickly align with what is ultimately chosen. The further we move from traditional approaches, the more compelling the rationale should be. Exploratory approaches could move the field forward without jeopardizing inclusion of multiple sponsors of neutralizing abs and direct acting antivirals based on concern for how success will be determined, by others.

Best regards

## Lynn

Gilbert 'Lynn' Marks, MD
Senior Advisor to BARDA, Office of the Director
Tunnell Government Services supporting the mission of:
Biomedical Advanced Research and Development Authority (BARDA)
Assistant Secretary for Preparedness and Response (ASPR)
Department of Health and Human Services (HHS)
200 C St SW
O'Neill Bldg
Washington, DC 20024

From: Karen Lynn Price	b6	}			
Sent: Friday, May 22, 20	020 12:07 AM				
To: Michael Hughes	b6	; LaVange	, Lisa M	<b>b6</b> ⊳; Pr	oschan, Michael
(NIH/NIAID) [F] :	h6	Fron Joseph Lir	b6	Ada	m. Stacev (FNIH) [T]
b6 ; cur	rier.judith	b6	; Eric Hughes	b6	🗦; Sandeep
Menon I (FDA/CDER)	b6	; Read, Sarah (NIH/	NIAID) [E]	b6 };	Price, Dionne
(FDA/CDER)	b6	: Rubin. Daniel B. (F	DA/CDER)	b6	: Farley, John
(FDA/CDER) b6	b6 ;	smith.davey	b6		chew.kara
b6	; Wohl, David	A   <b>b6</b>	>; Fisch	er, William A. II	·
b6	; Javan,	Arzhang (NIH/NIAID	) [C] <del>b6</del>	خ	Jhoanna <b>₹bo</b> i
		H/NIAID) [E]			
Marks, Gilbert (OS/ASPI	R/BARDA) (CTR)	b6	Kozak, Marin	a (OS/ASPR/BARI	DA)
b6					··-·-,
<b>Cc:</b> DeMarcus, Forrest <	b6	; Tountas,	Karen (FNIH) [T]	b6	j; Wachtel, Jonathan
<pre><jwachtel@deloitte.com< pre=""></jwachtel@deloitte.com<></pre>					
roa.jhoanna 🛴	b6	; Smith, David	b6	; Paul Klek	otka
b6	Ajay Nirula {	b6	}; Elsaid, Olivia <	oelsaid@deloitte.	com>; Robert Jan
Benschop {	b6 >;	Lei Shen k	)6		
Subject: Re: [EXTERNAL	Re: Confirmed: A	ACTIV TX-Clinical mA	b Outpatient WT N	leeting-3	

## Thanks Lisa and Michael.

Working now to put together more details on the modeling and developing a simulation plan. We look forward to discussing in our stats meetings soon. Whether we end up with Bayesian or frequentist approach, simulation of this design will be required in order to better understand the operating characteristics.

I do think it is important we keep in mind that for a master protocol such as this, the specific model used and associated priors will necessarily change over time. So the intent would be to put the basic framework of the model into the master protocol, but specify the model, agent's specific sample size, and operating characteristics assessed via simulation in the associated agent's appendix. One advantage of this is that in order to navigate through these many agents efficiently and effectively we necessarily need to learn over time and formally incorporate that learning into our modeling. For example, we will learn more over time about the relationship between the symptomatic endpoints/viral endpoints/clinical endpoint (hospitalization/er visit/death) and that learning needs to be incorporated into future agent's modeling, which should also lower sample size and improve precision/decision making across these agents. It is presently unclear to me how we can effectively evaluate several agents / borrow placebo / incorporate prior knowledge we will gain over time / etc without a Bayes approach, but I look forward to discussing in our stats meetings.

Thanks, Karen

	L.O.				
From: Michael Hughes					
<b>Date:</b> Thursday, May 21 <b>To:</b> "LaVange, Lisa M"	., 2020 at 12:54 PW		an Michael (N	NIH/NIAID) [E]"	
b6	, "Eron, Joseph		b6		n, Stacey (FNIH) [T]"
	rrier.judith"	b6	. <del></del>	ic Hughes	b6
Sandeep Menon	b6	:	ead.sarah"	b6	l, "Price, Dionne
(FDA/CDER)"	b6	'	niel B. (FDA/CD		b6
"Farley, John (FDA/CDEI		ž	Karen Price	b6	· · · · · · · · · · · · · · · · · · ·
"smith.davey"		b6		i j	>, "chew.kara"
b6	>, "Wohl, David	A'	b6	, "Fischer,	William A. II"
b6	>, "javan.a	rzhang"	b6	, "Roa, Jh	noanna" <b>b6</b>
b6		kim.peter"[	b6	"li.jonat	
i	, "Marks, Gilbert (C	DS/ASPR/BAR	DA) (CTR)" [	b6	, "Kozak, Marina
(OS/ASPR/BARDA)"	b6	<u></u>	-	· · · · · · · · · · · · · · · · · · ·	······
Cc: "DeMarcus, Forrest"			•	n (FNIH) [T]" <	b6
"Wachtel, Jonathan" <jv< td=""><td></td><td></td><td></td><td>@deloitte.com&gt; <b>b6</b></td><td></td></jv<>				@deloitte.com> <b>b6</b>	
(NIH/OD) [E]"		oa.jhoanna"	i		"Smith, David"
"Elsaid, Olivia" < <u>oelsaid</u>	, Paul Klekot	\	b6	, Ajay Nirula b6	b6 ; ⇒, Lei Shen
b6	wdeloitte.com/, N	ODEIL Jan Dei	ischop[	D6	P, Lei Sileii
Subject: [EXTERNAL] Re	· Confirmed· ACTIV	/ TX-Clinical r	nAh Outpatien	nt WT Meeting-3	
		.,,			
EXTERNAL EI	<b>VIAIL:</b> Use cautio	n before rep	olying, clicking	g links, and ope	ening attachments.
LI; I ico					
Hi Lisa,					
That's fine. Perhaps you	and Karen could	circulate som	e brief details	of the Bayesian	model framework and
associated priors for eac	h outcome measure	e you are env	isaging? I t	hink that would	help in moving things
along.					
Looking forward to disc	alcoino				
Looking forward to disc	ussing,				
Michael					

From: LaVange, Lisa M	İ	b6					
Sent: Thursday, May 2	1, 2020 1	:34 PM	4				
To: Michael Hughes; Pr	roschan, I	Michael (NIH/I	ا ( IAID   [E]; Eron	loseph J Jr; Ad	lam, Stacey (F	NIH) [T]; curri	er.judith; Eric
Hughes; Sandeep Men	on; read.s	sarah; Price, D	ionne (FDA/CDEF	R); Rubin, Dani	iel B. (FDA/CI	ER); Farley, Jo	ohn (FDA/CDER);
Karen Lynn Price; smitl	h.davey;[ <u> </u>	b6	chew.kar	a; Wohl, Davi	d A; Fischer, \	Villiam A. II; ja	avan.arzhang;
Roa, Jhoanna; b	6	; kim.peter; li.j	jonathan; Marks,	Gilbert (OS/A	SPR/BARDA)	(CTR); Kozak,	Marina
(OS/ASPR/BARDA)							
Cc: DeMarcus, Forrest;	Tountas,	Karen (FNIH)	[T]; Wachtel, Jon	athan; Elizabe	eth Kim; Parke	r, Ashley (NIH	I/OD) [E];
roa.jhoanna; Smith, Da	vid; Paul	Klekotka; Ajay	Nirula; Elsaid, O	livia; Robert Ja	an Benschop;	Lei Shen	
Subject: RF: Confirmed	I. ACTIV T	X-Clinical mak	Outnatient WT	Meeting-3			

Thanks, Michael. I believe it is premature to submit the protocol to your internal review committee. My takeaway from yesterday's meeting was that the next step would be for the subgroup of statisticians to meet to discuss the simulations required for the revised trial design. The proposed revisions to the design are needed, in my opinion, to give us the type of flexible, fast-moving master protocol we need to screen a large amount of monoclonal antibodies. But we need to work out some of the design details, so let's have that next meeting as planned. Hoping we can schedule it for some time tomorrow and will work with Stacey to find a time.

Lisa

From: Michael Hughes	'	b6				
Sent: Thursday, May 2	1, 2020 11:03 AM					
To: Proschan, Michael	(NIH/NIAID) [E]		b6	; LaVar	nge, Lisa M	
b6	>; Eron, Joseph J.	Jr	b6	; Ac	dam, Stacey (	FNIH) [T]
<b>b6 b6 b</b> ; cu	rrier.judith	b6		; Eric Hughes	S (	b6
Sandeep Menon!	b6	" >: r	ead.sarah	<b>b6</b>	>: F	Price. Dionne
(FDA/CDER) Farley, John (FDA/CD) smith.davey David A b	b6	⊳; Rubin, I	Daniel B. (	FDA/CDER)		b6 ;
Farley, John (FDA/CD)	ER) be	3	; Karen I	_ynn Price	be	6
smith.davey	b6		chev	v.kara[	b6	>; Wohl,
David A b	6 ⊳; F	ischer, Willi	am A. II <		b6	javan.arzhang
b6	∵>; Roa, Jhoanna		<b>b6</b>		kim.peter	
b6 ▶	: li.ionathan	h6	}; Ma	irks, Gilbert (	ÖS/ASPR/BA	ARDA) (CTR)
b6	>; Kozak, Marir	na (OS/ASPF	R/BARDA	.) [	b6	
Cc: DeMarcus, Forrest	b6	þ; ˈ	Γountas, k	Caren (FNIH)	[T] <	b6 ;
Wachtel, Jonathan < jw	achtel@deloitte.co	m>; Elizabet	th Kim < <u>e</u>	lkim@deloitt	e.com>; Park	er, Ashley (NIH/OD)
[E] <b>b6</b>	>; roa.jhoann >; Paul Kleko	a	b6	>; Sm	ith, David	
b6	; Paul Klek	otka 🖣	b6	>; A	jay Nirula	
b6	⊳; Elsaid, Olivia <	<oelsaid@de< td=""><td>loitte.com</td><td>&gt;; Robert Jan</td><td>Benschop</td><td></td></oelsaid@de<>	loitte.com	>; Robert Jan	Benschop	
	>; Lei Shen				-	
Subject: Re: Confirme	d: ACTIV TX-Cli	nical mAb O	utpatient \	WT Meeting-	3	

Hi All:

The ACTG team was hoping to submit the A5401 protocol tomorrow to the NIAID Clinical Science Review Committee for their review. The protocol design uses standard (widely-used) statistical methods for interim and final analyses but we received the feedback (attached) from ACTIV about moving to fully use Bayesian methods, so wanted to respond and get thoughts back as this is a substantial change --- and would mean that we would not be able to send for CSRC tomorrow.

I have particular concerns about the need to use the Bayesian paradigm, particularly for Phase III. For a given agent, the Phase 3 study is a fairly simple study involving evaluations for safety, clinical symptoms, and the primary outcome measure of hospitalization/death. We proposed to use standard group sequential monitoring methods which are flexible (using the Lan-DeMets approach for flexible timing of interim analyses with an O'Brien and Fleming type stopping guideline). I think the seamless phase II to phase 3 aspect of the design can be incorporated into this flexible approach by just considering the "look" at the data at the end of phase II as one "look" at the phase 3 primary outcome. This provides protection for the Type I error rate for each specific agent. We can overlay a the possibility of a simple futility rule, eg at >=50% enrollment, to allow stopping for lack of effect (can be justified using a Type II spending boundary, conditional power, or even a Bayesian type rule).

I think this is all quite straightforward. I worry that putting the Phase 3 trial into the Bayesian paradigm gains very little but adds complexity in terms of having to confirm that any Bayesian decision rule does protect Type I error rate for regulatory purposes, and in terms of explaining to many different companies and ultimately to a broad audience. In addition, if the study does go global, it increases the complexity of explaining to IRBs and other review groups.

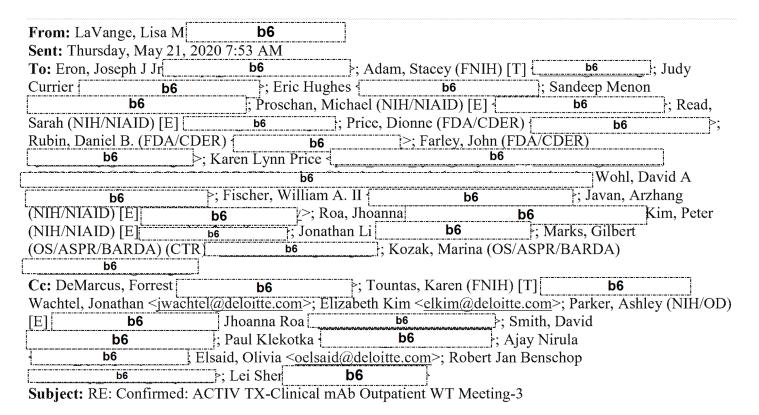
I would prefer to leave Phase 3 using standard (widely used) statistical methods. I would also favor using standard methods for analysis of Phase 2 data but do agree that Bayesian analyses might also be used for the main efficacy outcome measures to provide an additional perspective in decision-making --- though the main graduation rules (eg observing an absolute 20% reduction in % positive for SARS-CoV-2 at an measurement time, and/or a 20% reduction in mean symptom duration) are straightforward and well-powered.

Ιw	vould welcome feedback.	
Ma	any thanks,	
Mi	ichael	

From: Proschan, Michael (NIH/NIAID) [E]   b6
Sent: Thursday, May 21, 2020 8:52 AM
To: LaVange, Lisa M; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep
Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER)
Karen Lynn Price; smith.davey; Michael Hughes; b6 ; chew.kara; Wohl, David A; Fischer,
William A. II; javan.arzhang; Roa, Jhoanna; b6 kim.peter; li.jonathan; Marks, Gilbert
(OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)
Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley
(NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop;
Lei Shen
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

I think the question is whether we could stop early for efficacy as well as stopping early for futility. That could certainly be incorporated if you think there is a realistic possibility of crossing an efficacy boundary after only 50 people. At the halfway point, the O'Brien-Fleming-like spending function boundary for the z-score is close to 3, so you would have to see a very large z-score to stop that early for efficacy.

## Mike.



This seems reasonable to me. We can define any basis that we think will be important for dropping dose arms or entire agents, having little to go on at this point in terms of what best predicts hospitalizations.

Lisa

From: Eron, Joseph J Jr							
Sent: Wednesday, May	20, 2020 6:2	3 PM		·			
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b6 b6 Sarah (NIH/NIAID) [E]	; LaVai	ige, Lisa M	b6	;	Sandeep N	<b>Menon</b>	
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<b>b6</b>	; Elsaid, Ol	ivia <u><oelsaid< u=""></oelsaid<></u>	@deloitte.co	m>; Robert	Jan Bensch	юр	
b6	Lei S	Shen	<b>b6</b>	<b> </b> >			
Subject: RE: Confirmed	l: ACTIV TX	K-Clinical m	Ab Outpatier	nt WT Meeti	ng-3		

Here is my question for the group – especially Michael, John and Lisa

My question is whether there could be an interim "activity" analysis similar to the futility analysis listed below – the reason I ask is we have very little longitudinal data on the quantitative viral shedding and it is possible that this endpoint would have substantial power such that 50 patients per arm could provide an antiviral answer.

• If the Phase 2 portion of the Clinical mAb protocol is used for dose finding, this may be challenging with respect to size of the trial (number of treatment arms needed and available sample size per treatment arm). In addition, it may be appropriate to establish an interim futility analysis based on change in quantitative viral shedding to allow for discontinuation of a dose after e.g. 50 rather than 110 patients, or to allow early discontinuation of high doses due to safety findings.

Joe Eron MD

Professor of Medicine

University of North Carolina at Chapel Hill

School of Medicine

**b6** 

From: Adam, Stacey (FN			6						
Sent: Wednesday, May 2				1 (				<b>X</b> 7	T . 3.6
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Jhoanna Li b6	b6		Kim, Peter	(NIH/NI	AID) [E]	1	b6	}; Jo	nathan
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Wachtel, Jonathan < jwac									NIH/OD)
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Robert Jan Benschop		b6	Lei	Shen	b6		_}		
Subject: RE: Confirmed:			al mAb Outp	atient W	T Meeting	g-3			

Dear mAb Outpatient WT,

The FDA team that has been working with ACTIV and sitting in on our writing team meetings for this protocol would like to offer the attached thoughts for the group's consideration on tonight's call.

Also, attaching again the updated synopsis that was discussed with the mAb Steering Committee earlier today.

Thanks,

Stacey

## Stacey J. Adam, PhD Director, Cancer Research Partnerships **b6** | Mobile: b6 Direct: Join Zoom Meeting b6 Meeting ID: b6 Password: **b6** One tap mobile US (Germantown) b6 US (Chicago) Dial by your location US (Germantown) US (Chicago) US (New York) US (Tacoma) US (Houston) US (San Jose)

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Subject:	RE: ACTIV Preclinical working group (Friday meeting)
Attachments:	PRECLINICAL _Working Group_Agenda_20200522_d1.pptx; Animal Model Summaries.zip
Hi all,	
ili ali,	
	tached some materials to aid in our discussion today.
* The fi	rst attachment contains the agenda as well as our WG's objectives and timeline.
* The se	econd attachment is a folder with the Animal Model 'one-pager' summaries.
	, č
Diago let us l	know if you have any questions. Look forward to our discussion tomorrow.
riease iet us r	thow if you have any questions, Look forward to our discussion tomorrow.
Best,	
Joe and Rosa	
_	ppointment
From: Menets	ski, Joseph (FNIH) [T]
Sent: Tuesday	y, April 14, 2020 6:48 PM
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(FNIH) [T]; Jan	nes, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan;
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Subject: ACTI	V Preclinical working group (Friday meeting)
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**Start**: 5/22/2020 6:00:00 PM **End**: 5/22/2020 6:30:00 PM

Show Time As: Tentative

Required Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo Attendees: (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda

Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters,

Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]; Brown, Jeremy (NIH/NINDS) [E];

Bharucha_David; Gavin, Brian; Sadeh, Jonathan; Harler, Mary Beth

Optional Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Melsheimer, Rich [CNTNL]

Dear ACTIV TX-Clinical Master Protocol Subgroup,

For this meeting today, we have decide to split this meeting into two meetings to make most efficient use of everyone's time. This first 30 minute meeting will be the entire group with the companies for ACTIV-1 to discuss the next steps for this protocol. The second 30 minutes will now become a meeting of the mAb Steering Committee to finalize some decisions for the ACTIV-2 protocol that need to be completed by EOD today.

Thanks for your understanding.

Please find attached the slides for this first meeting today.

Thanks, Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/22/2020 3:17:22 PM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes ]; LaVange, Lisa M **b6** Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price b6 ; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner ; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert. Mar]CC: Demarcus 5 Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras] Subject: ACTIV mAb Steering Committee Meeting Location: Start: 5/22/2020 6:30:00 PM End: 5/22/2020 7:00:00 PM Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E]; Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O

Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR)

Optional

Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]

Attendees:

Dear ACTIV TX-Clinical mAb Steering Committee,

This meeting will serve to finalize our decision for the inpatient mAb network and discuss any final outstanding questions for the ACTIV-2 outpatient protocol.

We could not get full quorum for the 1pm meeting, so we thought we would shoot for this time which many of you already had blocked on your calendars. Apologies to the few folks who might not be able to attend.

Thanks,

Stacey

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	(FDA/CDER)		b6	arks, Gilbert (C	3/A3FN/DANL	)A) (CIN)			;, raney, John
CC:	Demarcus[	<u> </u>	b6	i F. Tount	as, Karen (FN	IH) (T) :	h6		tel, Jonathan
· · ·	L	leloitte c		beth Kim [elkir	n@deloitte.co	ml· Parker	r Ashley (N		cci, Jonathan
	_		_	ge Administrati		Jilij, i dikei	i, Asilicy (i	(III) (OD) [E]	
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Attendees:	myr oil !		a						
Dear ACTIV	TX-Clinic	al mAb	Steering	g Committee	<b>&gt;</b> ,				
This meeting questions for					the inpatien	t mAb ne	twork an	d discuss a	ny final outstanding
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From:	Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent:	5/22/2020 5:59:47 PM
То:	Bascles, Lionel b6 ; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry b6 ; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers , Betsy  b6 ; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos  b6
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura  b6 ]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri
	<b>b6</b> ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike
	b6 ; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]
CC:	Wachtel, Jonathan [jwachtel@deloitte.com]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis];
	Hughes, Eric <b>b6</b> ; Jansen, Kathrin <b>b6</b> ; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John  b6   Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana  b6 ; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative]
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
	Heaton, Penny b6 ; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li,
	Rose <b>b6</b> ; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy  b6 ; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin    b6
	[/o=ExchangeLabs/ou=Exchange Administrative Group  (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Minnich, Beth
	(NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora

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	<b>b6</b> ; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject:	ACTIV Clinical Trial Capacity Working Group - reporting meeting
Location:	b6
Start:	6/2/2020 1:00:00 PM
End:	6/2/2020 2:00:00 PM
Show Time As:	• •
Recurrence:	Weekly
	every Tuesday from 9:00 AM to 10:00 AM
Required	Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C];
Attendees:	Doroshow, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzine; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri;
	Stein, Peter (FDA/CDER); Vincent, Mike; Weinmann, Gail
Optional	Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah
Attendees:	(NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E]
	b6 ; Carluccio, Dana; Cheryl (FNIH) Melencio [T] b6 ; Gonzalez, Nina; Heaton,
	Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Hill, Zoe (NIH/NHLBI) [C]; Minnich, Beth;
	Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] b6
	Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]
CT Composity	wanting grown members. Many thente for all the head work that you have not into meeting our ACTIV
	working group members, Many thanks for all the hard work that you have put into meeting our ACTIV oking forward to operationalizing the outcomes of your efforts. Let's continue to meet regularly through the
	e (once a week) to continue to build out the inventories of CROs/SMOs/Networks/Sites and
	ficiencies, where needed, and, to integrate with other ACTIV working groups in support of protocol
implementation	on (treatment and prevention). Best regards, Karen
Karen Tounta	s is inviting you to a scheduled Zoom meeting.
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From:	Tountas, Karen (I (FYDIBOHF23SPE								1]	
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	(NIH/NCATS) [C]		b6	; Dorosh	ow, James (	NIH/NCI)	E][	b6	Garn	ner, Carlos
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	b6	; Fe	erguson, Su	e	b6					
CC:	Wachtel, Jonatha	an [jwachte	el@deloitte	.com]; Colvi	s, Christine	(NIH/NCA	ΓS) [E]	b6	);	Hughes,
	Eric	b6	]; Janse	en, Kathrin		b6	; Lc	wy, Douglas (	NCI)	b6
	Read, Sarah (NIH	/NIAID) [E		b6	; Young, Jo	hn	b6		Adam, Sta	acey (FNIH)
	[T] <b>b6</b>	; And	erson, Marg	aret [marga	nderson@d	leloïtte.coi	m]; Parke	r, Ashley (NIH	/OD) [E]	
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	[ningonzalez@de	eloitte.com	n]; Heaton, I	Penny [	b6		; Jame	s, Stephanie (	FNIH) [T]	
	b6	; Li, Rose		b6	); Me	enetski, Jo	seph (FNI	H) [T] [	b6	];
	Qashu, Felicia (N	IH/OD) [E]		b6	; Santos, M	lichael (FN	IH) [T]	b6		sson, Nancy
		b6		; Wholley	David (FNII	⊣) [T] [	b6	;]; Criffie	eld, Robin	
	b6	·	]; Hamilt	ton, Nancy		b6		; Hill, Zoe (N	IIH/NHLBI)	[C]
	b6	]; Minnich	, Beth	b6	]];	Mueller-R	eichenste	in, Petra [pet	ra.mueller	-
	b6		Pico, Dia،	nna (NIH/NI	HLBI) [C]	b6		; Quadros, No	ora	
	<b>b6</b>		; Katz, Reb	ecca (NIH/N	ICATS) [E]["	k	6	; Culp, Mic	helle (NIH/	/OD) [E]
	b6	; G	adbois, Elle	n (NIH/OD)	[E]	b6	j; Kei	nny, Dermot		
			b6							
Subject:	ACTIV Clinical Tri									
Attachments:			; Untitled Attachment; Canceled: ACTIV Clinical Trial Capacity Working Group - reporting							
	meeting; Untitle	d Attachme	ent; Untitle	d Attachme	nt					
Location:				b6						
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Recurrence:	Weekly									
	every Tuesday fr									
Required	Tountas, Karen (									
Attendees:	Jim (NIH/NCATS)				_					
	Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzine; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Vincent, Mike; Weinmann, Gail; Kublin MD, MPH, James; Ferguson,									
		adhri; Steir	n, Peter (FD	A/CDER); Vi	ncent, Mike	; Weinma	nn, Gail ;	Kublin MD, M	PH, James;	; Ferguson,
- · ·	Sue									
Optional	Wachtel, Jonatha									Read, Sarah
Attendees:	(NIH/NIAID) [E];									
	b6				FNIH) Meler					na; Heaton,
	Penny; James, St									
	Nancy; Wholley,								1innich, Be	th;
	Mueller-Reichen							Katz [E]	b6	;
	Culn Michelle (N	IIH/OD) [E]	l· Gadhois F	Ilen (NIH/O	D) [F]: Kenn	v Dermot	· {	h6	/	

CT Capacity working group members, Many thanks for all the hard work that you have put into meeting our ACTIV mandate – looking forward to operationalizing the outcomes of your efforts. Let's continue to meet regularly through the month of June (once a week) to continue to build out the inventories of CROs/SMOs/Networks/Sites and innovation/efficiencies, where needed, and, to integrate with other ACTIV working groups in support of protocol implementation (treatment and prevention). Best regards, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting		
	b6	
Meeting ID: <b>b6</b> Password: <b>b6</b> One tap mobile		
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From:	Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP					
	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]					
Sent:	5/22/2020 5:59:49 PM					
То:	Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group					
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel					
	b6 ; Cohen, Myron b6 ; Corey, Larry b6 ;					
	Victoria Davey b6 ; Desrosiers , Betsy b6 ; Dickens, Jim					
	(NIH/NCATS) [C] b6 ; Doroshow, James (NIH/NCI) [E] b6 ; Garner, Carlos					
	b6 Goff, David (NIH/NHLBI) [E] b6 ; Kurilla, Michael (NIH/NCATS) [E]					
	b6 ]; Mensah, George (NIH/NHLBI) [E] b6 ]; Nayak, Seema (NIH/NIAID) [E]					
	b6 Payton, Manizhe (NIH/NIAID) [E] b6 ; Resnansky, Laura					
	b6 ; Sizemore, Christine (NIH/FIC) [E] b6 ; Srinivasan, Badhri					
	b6 ; Stein, Peter (FDA/CDER) b6 ]; Vincent, Mike					
	b6 Weinmann, Gail (NIH/NHLBI) [E] b6 ; Kublin MD, MPH, James					
	<b>b6</b> ; Ferguson, Sue [s <b>b6</b> ]					
CC:	Wachtel, Jonathan [jwachtel@deloitte.com]; Colvis, Christine (NIH/NCATS) [E] b6 ;; Hughes,					
	Eric b6 ]; Jansen, Kathrin b6 ]; Lowy, Douglas (NCI) b6					
	Read, Sarah (NIH/NIAID) [E] b6 ; Young, John b6 ; Adam, Stacey (FNIH)					
	[Т] b6 ; Anderson, Margaret [ b6 ]; Parker, Ashley (NIH/OD) [Е]					
	b6 ]; Carluccio, Dana b6 ; Melencio, Cheryl (FNIH) [T]					
	b6 Gonzalez, Nina [ningonzalez@deloitte.com]; Heaton, Penny b6 ;					
	James, Stephanie (FNIH) [T] b6 ; Li, Rose b6 ]; Menetski, Joseph (FNIH) [T]					
	<b>b6</b> ; Qashu, Felicia (NIH/OD) [E] <b>b6</b> ; Santos, Michael (FNIH) [T]					
	b6 ; Tuvesson, Nancy b6 ; Wholley, David (FNIH) [T]					
	b6 ]; Criffield, Robin b6 )]; Hamilton, Nancy					
	b6 ; Hill, Zoe (NIH/NHLBI) [C] b6 ; Minnich, Beth					
	b6 ; Mueller-Reichenstein, Petra b6 ]; Pico, Dianna					
	(NIH/NHLBI) [C]   b6   Quadros, Nora   b6   Katz, Rebecca (NIH/NCATS) [E]					
	<b>b6</b> ]; Culp, Michelle (NIH/OD) [E] <b>b6</b> ; Gadbois, Ellen (NIH/OD) [E]					
	/o=ExchangeLabs/ou=Exchange Administrative Group					
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Kenny, Dermot					
	<b>b6</b>					
	1					
Subject:	ACTIV Clinical Trial Capacity Working Group - reporting meeting					
Attachments:	: Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment					
ocation: b6						
	<u> </u>					
Start:	6/2/2020 1:00:00 PM					
End:	6/2/2020 2:00:00 PM					
Show Time As:	Tentative					
Recurrence:	Weekly					
	every Tuesday from 9:00 AM to 10:00 AM					
Required	Tountas, Karen (FNIH) [T]; Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens,					
Attendees:	Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike;					
	Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzine; Resnansky, Laura; Sizemore, Christine (NIH/FIC)					
	[E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Vincent, Mike; Weinmann, Gail; Kublin MD, MPH, James; Ferguson,					
	Sue					
Optional	Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah					
Attendees:	(NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E]					
	<b>b6</b> ; Carluccio, Dana; Cheryl (FNIH) Melencio [T] ( b6 ; Gonzalez, Nina; Heaton,					
	Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuvesson,					
	Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Hill, Zoe (NIH/NHLBI) [C]; Minnich, Beth;					
	Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] ( <b>b6</b> ;					
	Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Kenny, Dermot; <b>b6</b>					
	Carp, whenche (Miny OD) [L], Caabots, Lifer (Miny OD) [L], Renny, Dennot, [ DO					

CT Capacity working group members, Many thanks for all the hard work that you have put into meeting our ACTIV mandate – looking forward to operationalizing the outcomes of your efforts. Let's continue to meet regularly through the month of June (once a week) to continue to build out the inventories of CROs/SMOs/Networks/Sites and innovation/efficiencies, where needed, and, to integrate with other ACTIV working groups in support of protocol implementation (treatment and prevention). Best regards, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/22/2020 6:35:02 PM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes b6 ; LaVange, Lisa M b6 ; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price b6 ; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner ; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda] ; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative CC: Demarcus Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras] Subject: **ACTIV mAb Steering Committee Meeting** Location: b6 Start: 5/22/2020 6:30:00 PM

5/22/2020 7:00:00 PM End:

Show Time As: Tentative

Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E]; Required Attendees: Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O

Garner; Bugin, Kevin (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER)

Optional

Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]

Attendees:

Dear ACTIV TX-Clinical mAb Steering Committee,

This meeting will serve to finalize our decision for the inpatient mAb network and discuss any final outstanding questions for the ACTIV-2 outpatient protocol.

We could not get full quorum for the 1pm meeting, so we thought we would shoot for this time which many of you already had blocked on your calendars. Apologies to the few folks who might not be able to attend.

Thanks,

Stacey

Join Zoom Meeting b6 Meeting ID: b6 Password: **b6** One tap mobile US (Chicago) **b6** US (New York) Dial by your location US (Chicago) US (New York) US (Germantown) US (San Jose) US (Tacoma) US (Houston) US (San Jose) Meeting ID: Password: **b6** Find your local number: b6

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC] 5/22/2020 8:13:29 PM Sent: To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Pao, William ; Plump, Andrew b6 ; Stoffels, Paul Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHE23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy ្ងំ Hughes, Eric **b6** ]; Jansen, Kathrin ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John ; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd] CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Chen, Helen [qingchen@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Perala, Mie ; Protasiewicz, Ann <u>b6</u> Riccobene, Kim b6 ; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Zottoli, Jessica b6 **ACTIV Executive Committee Teleconference** Subject: Location: b6 6/17/2020 4:00:00 PM Start: End: 6/17/2020 5:30:00 PM Show Time As: Tentative Required Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Attendees: Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Freire, Maria (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E] Optional Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Attendees: Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Zottoli, Jessica Cheryl Melencio is inviting you to a scheduled Zoom meeting. Join Zoom Meeting **b6** Meeting ID: b6 Password: b6 One tap mobile b6 US (New York)

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Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC] 5/22/2020 8:13:31 PM Sent: To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) ]; Disbrow, Gary (OS/ASPR/BARDA) [ ]; Dolsten, Mikael b6 b6 ; Fauci, Anthony (NIH/NIAID) [E] ; Gibbons, Gary (NIH/NHLBI) [E] b6 ; Marks, Peter (FDA/CBER) ; Pao, William ]]; Plump, Andrew [ ; Stoffels, Paul b6 /CDER) [ Woodcock, Janet (FDA ; Colvis, Christine (NIH/NCATS) [E] b6 b6 ; Hughes, Eric ; Desrosiers, Betsy ; Kurilla, Michael (NIH/NCATS) [E] ; Jansen, Kathrin b6 ]; Lowy, Douglas (NCI Read, Sarah (NIH/NIAID) [E] b6 ; Young, John Anderson, James (NIH/OD) [E] b6 ; Austin, Christopher (NIH/NCATS) [E] b₆ Burklow, John (NIH/OD) إريسي [E] Culp, Michelle (NIH/OD) ]; Freire, Maria (FNIH) [T] ; Lane, Cliff (NIH/NIAID) [E] Hallett, Adrienne (NIH/OD) [E] i b6 Myles, Renate (NIH/OD) [E] ; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) ]; Wolinetz, Carrie (NIH/OD) [E] ; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel] CC: Adam, Stacey (FNIH) [T] b6 ; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Chen, Helen [qingchen@deloitte.com]; Elsaid, Olivia [oelsaid@deloitte.com]; Gonzalez, Nina [ningonzalez@deloitte.com]; James, Stephanie (FNIH) [T] **b6** ]; Kim, Elizabeth [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] "]; Santos, Michael (FNIH) [T] ; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, لي Wachtel, Jonathan [jwachtel@deloitte.com]; Wholley, David (FNIH) [T] Karen (FNIH) [T] ; Barasch, Kimberly (NIH/NIAID) [C] ; Conrad, Patricia (NIH/NIAID) [E]] ; Dimishkov, Roxanne (NIH/NHLBI) [C] b6 McManus, Ayanna (NIH/OD) [E] ; Perala, Mie ; Protasiewicz, Ann b6 Thomas, Ashley (FDA/CDER) ; Riccobene, Kim b6 Wood, Gretchen (NIH/OD) [E] ; Togashi, Mieko (NIH/NCI) [E] Lowy, Douglas (NIH/NCI) [E] ; Lucas Smalldon Subject: **ACTIV Executive Committee Teleconference** Materials for June 17 ACTIV Executive Committee Teleconference Attachments: Location: Start: 6/17/2020 4:00:00 PM End: 6/17/2020 5:30:00 PM Show Time As: Busy Required Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E];

Required Attendees: Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Freire, Maria (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C];

Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Zottoli, Jessica; Lowy, Douglas (NIH/NCI) [E]; Lucas Smalldon

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Attendees:

Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Freire, Maria (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]

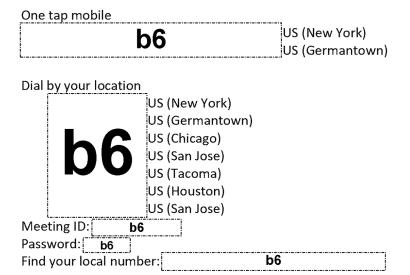
Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Zottoli, Jessica; Lowy, Douglas (NIH/NCI) [E]; Lucas Smalldon

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	[bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan
	[jwachtel@deloitte.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Perala, Mie
	<b>b6</b> Protasiewicz, Ann <b>b6</b> ; Riccobene, Kim
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	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Location:	b6
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Attendees:	Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock,
	Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael
	(NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Anderson, James (NIH/OD) [E];
	Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Freire, Maria (FNIH)
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	[E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Optional	Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James,
Attendees:	Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman,
	Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C];
	Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie;
	Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko
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C A -	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: To:	5/22/2020 9:53:16 PM Eric Hughes <b>b6</b> ; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
10.	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa];
	Ruxandra Draghia-Akli <b>b6</b> } Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative
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	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner
	b6 ]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	Maria [rosalvarez@deloitte.com]; Salathin, Carla
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	<b>b6</b> Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1];
	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account
	[FNIH@roseliassociates.com]
Subject:	Summary of ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12
Attachments:	2020-05-21_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting-Summary.pdf
Dear ACTIV T	X-Clinical Agent Prioritization Subgroup,
Please find at	tached the formal summary from our meeting yesterday. If you have any additions or amendments, please
contact me.	, , , , , , , , , , , , , , , , , , , ,
Thanks,	
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Stacey J. Ad	
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Research Par	
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/23/2020 1:23:29 AM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner Keith Gottesdiener ; Eric Hughes ; LaVange, Lisa M **b6** ; Amanda Peppercorn ; Proschan, Michael Menon b6 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael ; Wung, Peter /US 🕽 Pamela Tenaerts, M.D. ; Patterson, Amy (NIH/NHLBI) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy Beumont-Mauviel, Maria [JRDUS] **b6**; Peeters, Monika [JRDBE] Woodfall, Brian [JRDUS] **b6**; Van Heeswijk, Rolf [JRDBE] b₆ Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971e<u>efec944a68a94addd3b</u>24835f5-brownj7]; Bharucha_David ; Gavin, Brian **b6** ; Sadeh, Jonathan Harler, Mary Beth **b6** ; Macone, Erin CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Melsheimer, Rich [CNTNL] Subject: Follow-up to ACTIV TX-Clinical Master Protocol Subgroup Meeting #20 Attachments: ACTIV_Therapeutics-Clinical_Master Protocol Subgroup_22May2020_Meeting Notes.pdf

Dear ACTIV TX-Clinical Master Protocol Subgroup,

Please find the summary of todays call. If you have any additions or amendments, please feel free to send them to me.

As the action items articulate, I will be reaching out to the companies and a few MPSG members to arrange writing tea meetings next week. Please let me know if you would like to be on that team.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

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Subject:	ACTIV-2 Writing Team M	eeting				
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Subject:	ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Review Protocol
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	b6 LaVange, Lisa M b6 ; Sandeep Menon
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CC:	Demarcus <b>b6</b> Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
cc.	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan
	[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]
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	Smalldon b6 ; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio! b6 ; Chen, Helen Q. [qingchen@deloitte.com]
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Required Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah Attendees: (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; Kim, Peter (NIH/NIAID) [E]; Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR) Optional Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Attendees: Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Lucas Smalldon; Rose Li Central Account; Dana Carluccio; Chen, Helen Q. Stacey Adam is inviting you to a scheduled Zoom meeting. Join Zoom Meeting Meeting ID: Password: **b6** One tap mobile US (Germantown) **b6** US (Chicago) Dial by your location US (Germantown) US (Chicago) US (New York) US (Tacoma) US (Houston) US (San Jose) US (San Jose) Meeting ID: b6 Password: b6

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CC:	Demarcus <b>b6</b> ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
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	Paul Klekotka b6 Ajay Nirula b6 ; Lucas
	Smalldon [ b6 ]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana
	Carluccio <b>b6</b> ; Chen, Helen Q. [qingchen@deloitte.com]
Subject:	ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update
Attachments:	Adapt Out COVID CSRC 052520.pdf; a5401-d06-052520v2.docx; ACTIV_TX-Clinical_ACTIV-2 Writing Team & mAb
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	Stein, Peter (FDA/CDER); Carlos O Garner; Bugir	n, Kevin; Marks,	
	Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina	a (OS/ASPR/BARDA)	
Optional	Demarcus; Tountas, Karen (FNIH) [T]; Wachtel,	Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OI	D) [E]; Jhoanna Roa;
Attendees:	Eron, Joseph J Jr; Smith, David; Paul Klekotka; A	Ajay Nirula; Lucas Smalldon; Rose Li Central Acco	unt; Dana Carluccio;
	Chen, Helen Q.		

Dear ACTIV-2 Writing Team and ACTIV mAb Steering Committee,

We are looking forward to this joint meeting tomorrow in which the ACTIV-2 team will share their progress on the mAb outpatient master protocol with the Steering Committee. The team will review the current thinking within the protocol. Then they would like to solicit feedback from the Steering Committee about a few remaining questions that could still alter the protocol structure.

Please find attached the materials for tomorrow:

1. Meeting agenda

Thanks,

- 2. Current ACTIV-2 master protocol
- 3. Slides summarizing the current protocol

US (Chicago)
US (New York)
US (Tacoma)

Please note that the stats team is still working to insert the final design of the Bayesian framework that will be used for agents beyond the first drug(s) into the trial for progression from Phase 2 to 3 within the study. This framework will not apply to the early entrants since prior learnings will be needed to inform the Bayesian model.

In addition, the team is waiting on some critical feedback from the FDA about how to address company feedback for a Phase 1(ish) safety/dose "run-in" study protocol that could be paired with the master protocol and potentially be overseen by ACTIV.

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	b6 ; Kim, Peter (NIH/NIAID) [E]
Optional	Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa;
Attendees:	Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula
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	b6 Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER)
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner
	Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert
	(OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Farley, John
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]
CC:	Demarcus <b>b6</b> ; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
CC.	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan
	[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Chen, Helen Q.
	[qingchen@deloitte.com]
	[4m8anan@ dalamatataam]
Subject:	ACTIV mAb Steering Committee Meeting
Location:	b6
Start:	5/29/2020 6:00:00 PM
End:	5/29/2020 7:00:00 PM
Show Time As:	
Show time As.	
Required	Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E];
Attendees:	Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O
	Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER)
Optional	Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.
Attendees:	
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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	5/23/2020 5:17:02 PM
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	[F] <b>b6</b> Butterton loan b6 Judy Currier
	b6 ; Eric Hughes b6 ; LaVange, Lisa M b6
	Read, Sarah (NIH/NIAID) [E] b6 ; Karen Lynn Price b6 Higgs, Elizabeth
	(NIH/NIAID) [E] b6 ]; Woodcock, Janet (FDA/CDER) b6 ]; Stein, Peter
	(FDA/CDER) b6 ; Carlos O Garner b6 ; Bugin, Kevin (FDA/CDER)
	b6 ; Marks, Gilbert (OS/ASPR/BARDA) (CTR) 66 Farley, John
	(FDA/CDER) b6 ; Jens Lundgren b6
CC:	Demarcus b6 ; Tountas, Karen (FNIH) [T] b6 Wachtel, Jonathan
	[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Chen, Helen Q.
	[qingchen@deloitte.com]; Salathin, Carla b6
Subject:	ACTIV mAb Steering Committee Meeting
Attachments:	ACTIV_TX-Clinical_mAb Steering Committee Meeting_20200529.pdf
Location:	b6
Chaut	F/20/2020 C-00-00 PM
Start:	5/29/2020 6:00:00 PM
End: Show Time As:	5/29/2020 7:00:00 PM
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	Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E] Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER); Jens Lundgren Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q. Salathin, Carla ering Committee,
Please find att to the agenda	tached the proposed agenda and slides for tomorrow. Please let us know if we need to add anything else .
Thanks,	
Stacey	
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Join Zoom M	leeting (
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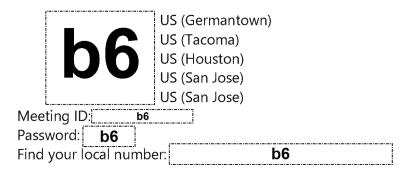
Meeting ID: b6

Password: b6
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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] 5/25/2020 7:43:44 PM Sent: Vincent, Mike b6 ]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange To: Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Bascles, Lionel b6; Corey, Larry [lcorey@fredhutch.org]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy ]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos b6 j; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura ]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative <u>Group (FYDIBOHF23SPDLT)/cn=Re</u>cipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wachtel, Jonathan [jwachtel@deloitte.com]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang] CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Jintanat Ananworanich ; Walker, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e577497e37b244168bd76c0b8827ca71-Robert.Walk]; Mason, Robin (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77156b112de94c439dbccb6894954618-Robin.Mason]; Hughes, Eric ; Criffield, Robin b6 ; Hamilton, Nancy
; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth Mueller-Reichenstein, Petra **b6**; Quadros, Nora; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group ; Quadros, Nora (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana ; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny b6 ; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose ]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH)

[T] [/o=ExchangeLabs/ou=Exchange Administrative Group

***************************************	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy    b6
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John
	b6
Subject:	ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments:	Clinical Trial Capacity Working Group Meeting Agenda_05262020.pdf
Location:	b6
Start:	5/26/2020 1:00:00 PM
End:	5/26/2020 2:00:00 PM
Show Time As:	Tentative
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Recurrence:	Weekly every Tuesday and Friday from 9:00 AM to 10:00 AM
Required	Vincent, Mike; Goff, David (NIH/NHLBI) [E]; Bascles, Lionel; Corey, Larry; Cohen, Myron; Davey, Victoria; Desrosiers ,
Attendees:	Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Garner, Carlos; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzine; Qashu, Felicia; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan,
	Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Mensah, George; Weinmann, Gail
Optional	Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Jintanat Ananworanich; Walker, Robert (OS/ASPR/BARDA);
Attendees:	Mason, Robin (OS/ASPR/BARDA); Hughes, Eric; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein, Petra; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] <b>b6</b> ;
	Zoe (NIH/NHLBI) Hill [C] b6 ); Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E
	b6 ); Carluccio, Dana; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski,
	Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John
	[E], Jansen, Kathini, Lowy, Douglas (NCI), Kead, Salah (NIH) NIAID) [E], Toding, John
Dear Colleag	ues, Attached is the Agenda for the Clinical Trial Capacity Working Group agenda. I am please to
let you know	that BARDA (Biomedical Advanced Research and Development Authority, U.S. Dept of Health and
Human Servi	ces) will join the meeting to talk about their CRO relationships. With best regards, Karen
Dear Clinical	Trial Capacity WG members, This will extend our full working group calls through the end of May.
	the need for further meetings at the end of the month. Many thanks for your participation! Karen
Join Zoom M	leeting b6
	Do
Meeting ID:	b6
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	US (Chicago)
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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] 5/26/2020 3:11:00 PM Sent: To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, b6; Eisner, Markb6; Gottesdiener, Keithb6; Hughes, Ericb6; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; **b6** ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Menon, Sandeep Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish b6; Peppercorn, Amanda b6; Poole, Mike [ b6; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric b6 ]; Jansen, Kathrin b6 ; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana , Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny b6 ; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose b6 ; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy 

	[/o=ExchangeLabs/ou=Exchange Administrative Group					
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth					
	b6	; Mueller-Reichenstein, Petra	b6	Pico, Dianna		
	(NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora					
	b6 ]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]					
Subject:	Summary and action	items - CT Capacity WG meeting #11				
Attachments:	Clinical_Trial_Capacit	ty_Working_Group_Meeting_11_Final.pdf				

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #11 (May 22, 2020) of the full working group. The summary from the call today will be distributed as soon as it is available. The next full working group meeting is scheduled for Friday, May 29 at 9 am eastern time USA.

With best regards, Karen

## Karen H. Tountas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852







Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	5/27/2020 12:00:04 AM
To:	Eric Hughes b6 Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa];
	Ruxandra Draghia-Akli <b>b6</b> Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel <b>b6</b> Colvis,
	Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John
	b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike
	<b>b6</b> Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange
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	Vincent, Michael <b>b6</b> ; Keith Gottesdiener <b>b6</b> ; Elliott Levy
	b6 Wung, Peter /US b6 Koroshetz, Walter (NIH/NINDS) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth
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	b6 ; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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CC:	Elizabeth Kim [elkim@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa
	Maria [rosalvarez@deloitte.com]; Salathin, Carla <b>b6</b>
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon
	<b>b6</b> ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange
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	Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account
	[FNIH@roseliassociates.com]; Chen, Helen Q. [qingchen@deloitte.com]
Subject:	Inquiry about the ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #13

Dear ACTIV Agent Prioritization Subgroup,

It has become apparent that our mAb Prioritizaiton Subteam will need to have a second meeting this week.

Since we are still working on getting back the data requested for this larger team, I was hoping this group would allow us to cancel this larger meeting and use the time to have just a meeting of our mAb Prioritizaiton Subteam.

This group will get an overall update on the progress of the TX-Clinical WG at our large WG meeting with both the Agent Prioritization and Master Protocol teams, and we will work to get individual meetings for the other Agent Prioritization Subteams on the books for next week if the data has been fully assembled.

Please let me know if you have any opposition to canceling the meeting to allow for the smaller group meeting. If a majority would prefer to keep the meeting, we will find another time for the small group.

Thanks, Stacey

## Stacey J. Adam, PhD Director, Cancer Research Partnerships Mobile: Direct: Stacey Adam is inviting you to a scheduled Zoom meeting. Join Zoom Meeting b6 Meeting ID: b6 Password: b6 One tap mobile US (Chicago) **b6** US (New York) Dial by your location US (Chicago)

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	b6 ]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange			
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	Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group			
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CC:	Demarcus L b6 Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative			
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan			
	[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]			
	[/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa			
	b6 ; Eron, Joseph J Jr b6 Smith, David			
	j; Paul Klekotka b6 Ajay Nirula b6 j; Lucas			
	Smalldon Rose Li Central Account FNIH@roseliassociates.com; Dana			
	Carluccio <b>b6</b> ; Chen, Helen Q. [qingchen@deloitte.com]			
Subject:	Materials for ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting			
Attachments:	ACTIV_TX-Clinical_ACTIV-2 Writing Team & mAb SteerCo Joint Meeting Agenda_0527020.pdf; a5401-d06-			
	052520v2.docx; Adapt Out COVID CSRC 052520.pdf			

Dear ACTIV-2 Writing Team and ACTIV mAb Steering Committee,

We are looking forward to this joint meeting tomorrow in which the ACTIV-2 team will share their progress on the mAb outpatient master protocol with the Steering Committee. The team will review the current thinking within the protocol. Then they would like to solicit feedback from the Steering Committee about a few remaining questions that could still alter the protocol structure.

Please find attached the materials for tomorrow:

- 1. Meeting agenda
- 2. Current ACTIV-2 master protocol
- 3. Slides summarizing the current protocol

Please note that the stats team is still working to insert the final design of the Bayesian framework that will be used for agents beyond the first drug(s) into the trial for progression from Phase 2 to 3 within the study. This framework will not apply to the early entrants since prior learnings will be needed to inform the Bayesian model.

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Thanks, Stacey	
Stacey J. Adam, PhD Director, Cancer Research Partnerships Direct: b6 Mobile: b6	<u> </u>
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	Smalldon ; Rose Li Central Account [FNIH@roseliassociates.com]; Dana		
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Subject:	ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update		
Attachments:	Adapt Out COVID CSRC 052520.pdf; a5401-d06-052520v2.docx; ACTIV_TX-Clinical_ACTIV-2 Writing Team & mAb		
	SteerCo Joint Meeting Agenda_0527020.pdf		
Location:	b6		
Start:	5/27/2020 5:00:00 PM		
End:	5/27/2020 6:00:00 PM		

Show Time As: Tentative

Required Attendees:		deep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sara Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Kare		
		b6		
	b6	; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; R	loa, Jhoanna	
	b6 ; Kim, Peter (NIH/NIAID) [E	]; Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Higgs, Eli	zabeth	
	(NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks,			
	Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Mar	rina (OS/ASPR/BARDA)		
Optional	Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa;			
Attendees:	Eron, Joseph J Jr; Smith, David; Paul Klekotk	a; Ajay Nirula; Lucas Smalldon; Rose Li Central Account; Dan	a Carluccio;	
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Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/27/2020 1:20:05 AM Sent: To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, uxandra b6 ; Eisner, Mark b6 ; Gottesdiener, Keith b6 Hughes, Eric b6 ; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; LaVange, Lisa ; Levy, Elliot <u>b6</u>]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep Patel, Naimish ( b6 ; Peppercorn, Amanda Poole, Mike b6 | Proschan, Michae **b6** Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn b6 ; Garner, Carl b6 Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy ; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda] CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy **b6** ; Jansen, Kathrin **b6** ; Kim, Elizabeth [elkim@deloitte.com]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)

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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
	b6 ; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
Subject: Attachments:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Wachtel, Jonathan [jwachtel@deloitte.com]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Tolman, Brett [btolman@deloitte.com]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Chen, Helen Q. [qingchen@deloitte.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd] COVID-19 Status Reports and Dashboards from VA and UC System Copy of DailyReport_20200522.xlsx; UC Report 5-22-20.pdf
Dear ACTIV T	X-Clinical Working Group,
	tached some initial RWD that the FDA team has been kind enough to give us access to and will update for ch week if we would find it useful.
useful as we	know if either our Agent Prioritization Subgroup or the Master Protocol Subgroup would find this data are prioritizing agents and planning trials. If so, I will work with Peter Stein to ensure our group gets the rmation at the proper cadence.
Please do not	share beyond the ACTIV group at this time.
Thanks,	
Stacey	
Stacey J. Ad	lam, PhD
Director, Car	acer
Research Par	
Direct:	b6 Mobile: b6
From: Stein, F	Peter <b>b6</b>
Sent: Monday	y, May 25, 2020 6:59 PM

## Stacey,

Subject: reports

To: Adam, Stacey (FNIH) [T]

Amy Abernathy is coordinating a group pulling in RWD from a number of sources — with daily reports from the VA and UC system. She has permission to have these shared with the ACTIV group — so I've attached reports from last week, and if useful, we can have these at whatever frequency we prefer.

Regards, Peter

Peter P. Stein, MD
Director, Office of New Drugs, CDER/FDA

From:	Adam, Stacey (FNIH) [T] [/O= (FYDIBOHF23SPDLT)/CN=RE				1]
Sent:	5/27/2020 2:24:49 AM				
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			b6	; Ajay Nirula	<b>b6</b> ; Chen,
	Helen Q. [qingchen@deloitt				
Subject:	Follow-up to ACTIV-2 Writin	g Team Meeting			
Attachments:	ACTIV_Therapeutics-Clinical	_Master Protocol Subg	roup_ACTIV-2 V	Writing Team Meeting Min	utes_20200526.pdf
Dear ACTIV-2	Writing Team,				
Deal ACTIV-2	willing realli,				
Please find at	tached the notes from toda	ay's meeting.			
As a brief upd	late, the questions have be	en email to Peter Ste	ein and John Fa	arley from the FDA, and	we will keep the
group posted	on what we hear.				
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Ti					
Thanks,					
Stacey					
Stacey J. Ada	ım. PhD				
Director, Can					
Research Part					
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F	or the National Institutes				
Direct:	<b>b6</b>   Mobile:	<b>b6</b>			
fnih.org	\				
11400 Rockvi	ille Pike, Suite 600, North I	Bethesda, MD 20852			
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Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From:	Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]						
Sent:	5/27/2020 3:42:28 AM						
To:			<b>b6</b>		j		
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	/		3d079e00a564963	9c6f1425f3bb075f-nax3]; Greg Gler	าท		
	b6	Cavaleri Marco	b6				
CC:		b	-	; Jeneffer H	aynes		
	b6	; Tolman, Brett [l	otolman@deloitte.	.com]; Menetski, Joseph (FNIH) [T]			
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria						
	[rosalvarez@deloitte.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD)						
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Brian Rosen						
	b6 ; Cheryl Keech [ckeech@Novavax.com]						
Subject:	Agenda for the Protec	ctive Immune Respo	nses Sub-Group m	eeting			
Attachments:	M_Cavaleri_regulator	y_framework_emer	gencies.ppt				

Dear Protective Immune Responses Sub-Group members,

We're looking forward to today's (Wednesday) meeting, at 9am ET (6am PT / 3pm CEST).

Since our last meeting, Marco kindly shared the attached document on EMA and member state regulatory pathways for vaccine use and approval. Unfortunately Marco won't be able to join this meeting, but has offered to discuss the EMA pathways at a future meeting.

Our recent meetings have focused primarily on understanding regulatory pathways for vaccine use and approval, and the types of evidence that factor into regulatory decisions for different pathways, with two presentations on upcoming sources of evidence (NIAID NHP challenge studies using sera/lgG/mAbs and CDC immunological studies). A key goal of this group is to facilitate vaccine developers to generate evidence that can support evaluation of vaccine efficacy. For today's meeting, we plan to discuss the different categories of evidence and identify priorities for ACTIV to engage to be supportive.

We look forward to the discussion. If you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T] Sent: Tuesday, May 26, 2020 12:19 AM

Subject: Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached notes and materials from our meeting last week. Thanks again to Donna and Natalie for presenting, and as always to Marion for her contributions to the regulatory pathways during the meeting and subsequently.

We will be in touch again soon regarding this week's meeting. Feel free to reach out any time with questions or suggestions.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T] Sent: Tuesday, May 19, 2020 8:56 AM

Subject: Agenda and Materials for today's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached two documents for today's Protective Immune Responses Sub-Group meeting (2pm ET / 11am PT / 8pm CEST):

- An updated table of pathways to vaccine use
- Notes from the last Sub-Group meeting (with my apologies for the delay)

For today's meeting, the agenda items are:

- Discussion of the updated pathways table and next steps
- An overview of the CDC's serology activities by Natalie

We're looking forward to the discussion today. As always, if you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President, Science

Foundation for the National Institutes of Health

**b6** fnih.org

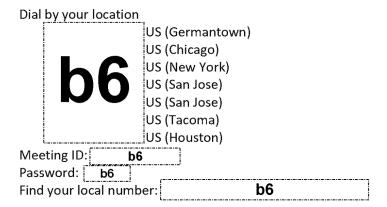
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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com] Sent: 5/27/2020 12:16:42 PM To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp] b6 ; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; ; Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas ]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar b6 (USA) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group CC: (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy Hughes, Eric b6 ; Jansen, Kathrin ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group [FYDIBOHF23SPDLT]/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@DELOITTE.com]; b6 ; Diamond, Michael Prabhavathi Fernandes ___ Dana Carluccio Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D  b6
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•	b6 ; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
	[bstratton@DELOITTE.com]
Subject:	RE: ACTIV Preclinical working group (Tuesday meeting)
Attachments:	PRECLINICAL _Working Group_Agenda_20200527_d2.pptx; 2020-05-22_Preclinical_WG_Summary_V1.docx
Hi all,	
Please find at	tached our agenda for today's meeting and the summary notes from our Friday meeting.
Look forward	to our discussion today.
Regards,	
Joe and Rosa	
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(NIT/NCATS)	b6 Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
	b6 Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas
Cihlar;	b6 (USA)
,	David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy;
	Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E];
	en (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa
	lizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana
	gos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C];
	Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E];
•	t (NIH/NIAII)) IFI: Nancy Haigwood: Stratton, Benjamin
Subject: ACTI	t (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin V Preclinical working group (Tuesday meeting)
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When: Wedne	V Preclinical working group (Tuesday meeting) esday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
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From: Alvarez, Rosa Maria [rosalvarez@deloitte.com] Sent: 5/27/2020 1:44:57 PM To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group b₆ (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp] **b6** Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; **b6** Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas ; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-gashufm]; Tomas Cihlar _____(USA) [ CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy Hughes, Eric **b6** ; Jansen, Kathrin ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel, Jonathan [jwachtel@DELOITTE.com]; Prabhavathi Fernandes ; Diamond, Michael **b6**; Rose Li b6 ;; Dana Carluccio b6 ; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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	[bstratton@DE	LOITTE.com]			0	,	,
Subject:		linical working grou		•			
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.ook forward	to our discuss	ion today.					
Regards,							
Rosa							
<b>Rosa M. Álvar</b> Deloitte <u>Consu</u> Mobile:							
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	z, Rosa Maria sday, May 27, 2	2020 8·17 AM					
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<ningonzalez@deloitte.com>; Simon, Dina (NIH/OD) [C] {

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onson, Samantha (NIH/NCAT<u>S) [E]</u>

Rodriguez, Robin D **b6**>; Baric, Toni C **b6** 

_;; Lowy, Douglas (NIH/NCI) [E]

_____>; Gonzalez, Nina

Burrus-Shaw, Cyndi (NIH/OD) [E]

; Dave Frankowski

	b6 ; Florence, Clint (NIH/NIAID) [E] b6 ; Nancy Haigwood
i	<b>b6</b> ; Stratton, Benjamin <bstratton@deloitte.com> <b>Subject:</b> RE: ACTIV Preclinical working group (Tuesday meeting)</bstratton@deloitte.com>
	Subject. N.E. Activities in working group (Tuesday meeting)
	Hi all,
	Please find attached our agenda for today's meeting and the summary notes from our Friday meeting.
	Look forward to our discussion today.
	Regards,
	Joe and Rosa
	Original Appointment
	From: Menetski, Joseph (FNIH) [T] 6 b6
	<b>Sent:</b> Tuesday, April 14, 2020 6:44 PM
	To: Menetski, Joseph (FNIH) [T]; b6
	b6
	b6 Baric, Ralph; b6 Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); b6
ï	b6 Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
i.	b6 Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas
	Cihlar; b6 (USA)
	Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy;
	Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E];
	Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa
	Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana
	Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]
	Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E];
	Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin
	Subject: ACTIV Preclinical working group (Tuesday meeting)
	When: Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
	Where: b6
	Changing time for preclinical WG
	Joseph Menetski is inviting you to a scheduled Zoom meeting.
	Join Zoom Meeting
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Sent: To:	5/27/2020 5:52:13 PM  Bascles, Lionel
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura  b6 ]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri  b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike
	b6 Wachtel, Jonathan [jwachtel@deloitte.com]; Weinmann, Gail (NIH/NHLBI) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]
CC:	Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John
	b6 ; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana b6 ]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Culp, Michelle
	(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gonzalez, Nina
	[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
	Heaton, Penny b6 ; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li,
	Rose <b>b6</b> ; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia
	(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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iubject:	Summary and action	items - CT Capacity WG meeting #12						
Attachments:	Clinical_Trial_Capacit	ty_Working_Group_Meeting_12_Final.pdf	f					

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #12 (May 26, 2020) of the full working group. The next full working group meeting is scheduled for Friday, May 29 at 9 am eastern US time.

With best regards, Karen

## Karen H. Tountas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

**b6** <u>fnih.org</u>

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Sent:	5/27/2020 10:18:57 PM	CIFILIN 13/CIV-D	CD873F0073048833E	ICF101C0343414-ADA	(1013)4]
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	[rosalvarez@deloitte.com]; S			DO	j Parker, Ashley (NIH/OD)
	[E] [/o=ExchangeLabs/ou=Ex				
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	[/o=ExchangeLabs/ou=Excha	-	•		
	(FYDIBOHF23SPDLT)/cn=Reci			5996d677257-wholley	d]; Melencio, Cheryl (FNIH)
	[T] [/o=ExchangeLabs/ou=Ex				
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	(NIH/NINDS) [E] [/o=Exchang				
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Subject:	Canceled: ACTIV TX-Clinical A			eeting	
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Dear ACTIV TX-Clinical Agent Prioritization team,

Thank you all for your responses. We will be converting this meeting into a mAb Subteam meeting for tomorrow in the hope of finalizing the minimal entry criteria.

Thank you all for your flexibility and understanding.

Stacey

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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=79a14013c7204460809b8c4213282808-tongtl]; Kurilla, Michael (NIH/NCATS)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	[/o=ExchangeLabs/ou=Exchange Administrative Group
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	b6 ; Isabel Ramsey b6 Sridhar, Saranya /US
	b6 ; Brian Rosen b6 ; Cheryl Keech b6 ;
	b6 Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	b6 ; Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell
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	Barton [/o=ExchangeLabs/ou=Exchange Administrative Group
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	<b>b6</b> Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group
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	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56fdbe4598a57b423d484dcf9f-offit.email];
	<b>b6</b> Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccba4e3caaf5eb5d3586b1cc-Jonathan.Se];
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	(CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Hotez, Peter Jay
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	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0712e2a723d741e8a78c4c8d37724ba1-sallyh]; Follmann, Dean (NIH/NIAID)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=42106b36984344e0914421f5fe408e7b-dfollmann]
Subject:	REVIEW REQUESTED by Thursday, 8pm ET: NIAID DSMB membership
Attachments:	NIAID DSMB suggested names.docx

Dear Vaccines Clinical Trials Sub-Group members (and cc'ing the Vaccines Working Group),

As mentioned in a previous email, NIAID is constituting a DSMB for the efficacy trials that are implemented with US government funding. They have collected 20 recommendations in the attached document (including some from this group), from which they plan to select 9 plus alternates in case not everyone accepts. They are looking for a specific mix of experience among the 9 (see header of the attachment).

Please review the document and provide any input you have on the proposed DSMB members by tomorrow (Thursday) at 8pm ET. Your feedback would be appreciated on any listed person that you would particularly recommend and any listed person that you would advise against inviting. We will share consolidated feedback from the group with Sally Hunsberger and Dean Follmann of NIAID; your individual feedback will not be shared.

Sally and Dean plan to join the start of our meeting tomorrow to answer any questions about the process, but we do not plan to discuss opinions about individuals in the meeting.

Please let us know if you have any questions. We look forward to your input.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President, Science

Foundation for the National Institutes of Health

b6 fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

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From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	5/28/2020 1:48:30 AM
To:	Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes
	b6 ; LaVange, Lisa M b6 ; Sandeep Menon
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	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham];
	Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; <b>b6</b> Kim,
	Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Kozak, Marina
	(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC:	Demarcus <b>b6</b> ; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
CC.	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan
	[jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa
	b6 Eron, Joseph J Jr b6 ; Smith, David b6 ; Paul Klekotka b6 Ajay Nirula b6 ; Chen,
	Helen Q. [qingchen@deloitte.com]
Subject:	Agenda for ACTIV-2 Writing Team Meeting
-	ACTIV_TX-Clinical_ACTIV-2 Writing Team Meeting Agenda_05282020.pdf
Attachments:	ACTIV_1X-Cliffical_ACTIV-2 writing real inteeting Agenda_05262020.pdf
D 4070/0	
Dear ACTIV-2	Writing Team,
Please find at	tached the proposed agenda for tomorrow's meeting. We may also have some outcomes and slides to
share from th	e stats meeting preceding this, but those will be distributed after that call.
Thanks,	
Stacey	
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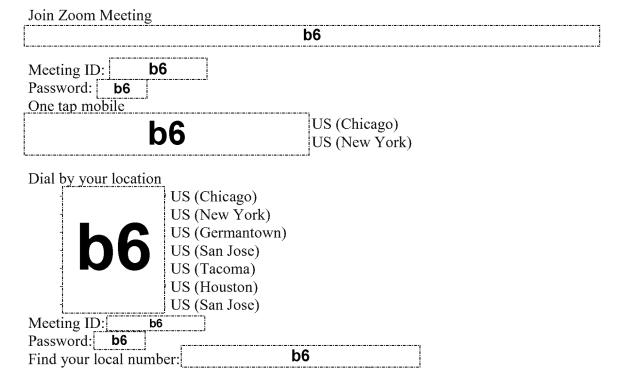
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10.	(FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes					
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cc:	Demarcus   b6  ; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative					
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	Helen Q. [qingchen@deloitte.com]					
Subject:	ACTIV-2 Writing Team Meeting					
	ACTIV_TX-Clinical_ACTIV-2 Writing Team Meeting Agenda_05282020.pdf					
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Required	Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah					
Attendees:	(NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price;					
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	b6 JEron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna;					
	b6 ; Kim, Peter (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA)					
Optional	Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa;					
Attendees:	Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Chen, Helen Q.					

Dear ACTIV-2 Writing Team,

Please find attached the proposed agenda for tomorrow's meeting. We may also have some outcomes and slides to share from the stats meeting preceding this, but those will be distributed after that call.

Thanks, Stacey



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/28/2020 4:54:28 PM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, b6 | Eisner, Mark | b6 | Gottesdiener, Keith | Hughes, Eric | b6 | Judy Currier b6 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [_________]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish b6 ; Peppercorn, Amanda b6 ; Poole, Mike b6 Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn ]; Garner, Carl <u>b6</u>; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy Jansen, Kathrin <u>b6</u>, Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Re			567c66b832ba	aa0-drl.helix.n];	Young, John	
	b6	; Biggs, Mary	b6	]; Butche	r, Tina	b6	
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	(FYDIBOHF23SPDLT)/cn=Re	ecipients/cn=5001a	f52dc4a427ea3	3d34f1e072f8c	b7-menetskijp];	James, Stephanie	e (FNIH)
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	(FYDIBOHF23SPDLT)/cn=Re	ecipients/cn=f0032	ef62ca343dfb4	bf79577e2aa8	d1-jamesst]; Wa	chtel, Jonathan	
	[jwachtel@deloitte.com];	Γolman, Brett [btolr	man@deloitte.	com]; Alvarez,	Rosa [rosalvarez	@deloitte.com];	
	Gonzalez, Nina [/o=Exchan	geLabs/ou=Exchan	ge Administrati	ve Group			
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	Li Central Account [FNIH@	roselias sociates.com					
	Smalldon (	b6		Benjamin [bstr	atton@DELOITTI	E.com];	
	b6	ˈm; Mollica, Linda /	/US	b6	; Qashu, Felici	a (NIH/OD) [E]	
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	(NIH/NHLBI) [E] [/o=Exchar	-	-	•			
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Subject:	ACTIV TX-Clinical Working	Group Meeting #8					
Attachments:	ACTIV_TX-Clinical_Working		uide 20200528	.pdf			
Location:	[	b6		11	)		
Start:	5/28/2020 5:00:00 PM						
End:	5/28/2020 6:00:00 PM						
Show Time As:	Tentative						

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]

Optional Attendees:

Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla;

From:	Eron, Joseph J Jr <b>b6</b>
Sent:	5/28/2020 6:45:14 PM
To:	Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam
	(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes
	b6 LaVange, Lisa M b6 ; Sandeep Menon
	b6 ; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham];
	Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	[/o=ExchangeLabs/ou=Exchange Administrative Group
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	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(170100111 2337011)/c11=Recipients/c11=4004c44300144047801311e70caa030c4 ARLE13.tda], Raiei Lyilli Filce
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	b6 ; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; <b>b6</b> Kim,
	Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Butterton, Joan
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Higgs, Elizabeth
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER)
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	Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC:	DeMarcus, Forrest
	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh];
	Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa
	b6 ; Smith, David b6 ]: Paul Klekotka b6
	Ajay Nirula <b>b6</b> ; Lucas Smalldon <b>b6</b> ; Rose Li Central Account
	[FNIH@roseliassociates.com]; Dana Carluccio <b>b6</b> ; Chen, Helen Q.
	[qingchen@deloitte.com]
Subject:	RE: ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update

I was referring to the paper and its implications for infectiousness

I think development of a quantitative assay with internal standards that will allow for more precise quantitation beyond just cycle number which might vary between assay runs is the way to go.

Joseph J. Eron MD Professor of Medicine Chief, Infectious Diseases Division **b6** Admin: Nate_Cooper@med.unc.edu From: Marks, Gilbert (OS/ASPR/BARDA) (CTR) Sent: Thursday, May 28, 2020 2:41 PM Adam, To: Eron, Joseph J Jr ; Bozzette, Sam (NIH/NCATS) [E] Stacey (FNIH) [T] T) Judy Currier ኑ; Eric Hughes **b6** LaVange, Lisa M { ); Sandeep Menon ;; Proschan, Michael (NIH/NIAID) [E] i>; Read, Sarah b6 (NIH/NIAID) [E] Price, Dionne (FDA/CDER) 🤄 🖟; Rubin, Daniel B. (FDA/CDER) { >; Farley, John (FDA/CDER ; Karen Lynn Price b6 b6 ; Wohl, David A ï>; Fischer, William A. II **b**6 b6 >; Javan, Arzhang (NIH/NIAID) [C] .<u>b6</u> _____, Roa, Jhoanna **b6** b6 Kim, Peter (NIH/NIAID) [E] : Butterton, Joan b₆ ; Higgs, Elizabeth (NIH/NIAID) [E] Woodcock, Janet (FDA/CDER) >; Stein, Peter (FDA/CDER) { b₆ Carlos O Garner ; Bugin, Kevin (FDA/CDER) ; Kozak, Marina (OS/ASPR/BARDA) b6 Tountas, Karen (FNIH) [T] Cc: DeMarcus, Forrest < ⊳; Wachtel, Jonathan <jwachtel@deloitte.com>; Elizabeth Kim <elkim@deloitte.com>; Parker, Ashley (NIH/NCI) [F] b6 Smith, David Jhoanna Roa b6 ; Paul Klekotka ; Lucas Smalldon ; Ajay Nirula b6 ; Rose Li Central Account <FNIH@roseliassociates.com>; Dana Carluccio **b6** Chen, Helen Q. <qingchen@deloitte.com> Subject: RE: ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting - Protocol Update Thanks Joe Cycle thresholds will be important to specify I would suggest. Amplifying non-infectious fragments vs correlating with what would suggest infectious virus begs for at least standardization of Ct. Or am I missing your point that we shouldn't bother with setting Ct...as long as it can be amplified no matter how many cycles, it would still be a positive? CDC colleagues may have more on this issue. Lynn From: Eron, Joseph J Jr Sent: Thursday, May 28, 2020 12:25 PM To: Bozzette, Sam (NIH/NCATS) [E] ∢ ; Adam, Stacey (FNIH) [T] **b6 Judy Currier** ; LaVange, Lisa M b₆ ; Eric Hughes Sandeep Menon b6 ት; Proschan, Michael (NIH/NIAID) [E] { Read, Sarah (NIH/NIAID) [E] 🏲; Price, Dionne (FDA/CDER) 🗒 ; Rubin, Farley, John (FDA/CDER) Daniel B. (FDA/CDER) Karen Lynn Price { b6 b6 Wohl, David A b6 Fischer, William A. II b6 b6 Javan, Arzhang (NIH/NIAID) [C] Roa, Jhoanna b6 Kim, Peter (NIH/NIAID) [E] 🖰 Butterton, Joan Higgs, Elizabeth (NIH/NIAID) [E] ; Woodcock, Janet (FDA/CDER) **b6** 🞚; Stein, Peter (FDA/CDER) b6 Carlos O Garner

**b6** 

Bugin, Kevin (FDA/CDER)

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; Marks, Gilbert (OS/ASPR/BARDA)

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(CTR) ₹ <b>b6</b>		ak, Marina (OS/ASPR/		D6	<u> </u>
Cc: DeMarcus, Forrest	·		as, Karen (FN	·	<b>b6</b> Wachtel, Jonatha
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Jhoanna Roa	b6	; Smith, David <			; Paul Klekotka
b6	; Ajay Niru	1	i	Smalldon	
b6	3	Chen, Helen Q. <			es.com>; Dana Carluccio
Subject: Re: ACTIV-2 V	Writing Team a				ol Update
I don't find this part	icularly reassu	ıring. As you know i	it is extreme	ly difficult to cu	ılture HIV from semen but
there is no doubt abo	out its infection	usness			
Joseph Eron MD					
Professor of Medicin	ne				
Division of Infection	ıs Disease				
UNC Chapel Hill					
h6					
<b>b</b> 6					
From: Bozzette, Sam (	NIH/NCATS) [E	] b6			
Sent: Thursday, May 2	28, 2020 11:45:	50 AM			
<b>To:</b> Adam, Stacey (FNI		<b>b6</b> >; Judy Curri	er ﴿	b6	; Eric Hughes
b6		·		; Sandeep Meno	
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(OS/ASPR/BARDA)	; iviarks, 0 <b>b6</b>	Gilbert (OS/ASPR/BAR	(DA) (CIK) 4	DO	; Kozak, Marina
Cc: DeMarcus, Forrest	·!	6 - Tount	as, Karen (FN	וווי) ודז 🗼 🖠	; Wachtel, Jonatha
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Smalldon !			i Central Acco	.2' " "	eliassociates.com>; Dana
Carluccio	<b>b6</b>	1.		chen@deloitte.c	
Subject: RE: ACTIV-2 V	Writing Team ar	′		<u> </u>	
Of interest re interpre	ting virology -[			b6	
Original Annaintm	ant				
Original Appointm From: Adam, Stacey (I	·	b6			
<b>Sent:</b> Saturday, May 2			lange Lica Ma	Sandean Mana	n; Proschan, Michael (NIH/NIAI
		- ·		•	; Farley, John (FDA/CDER); Kar
Lynn Price;		e, Diotilie (FDA/CDEN)	b6	er b. (I DA/CDEN)	
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ľ	b6	Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna;
Ľ	<b>b6</b> Kim, Peter (NIH/NIAID) [E]; Bozzette, Sar	m (NIH/NCATS) [E]; Butterton, Joan; Higgs, Elizabeth
(	NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter	(FDA/CDER); Carlos O Garner; Bugin, Kevin (FDA/CDER);
١	Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS,	/ASPR/BARDA)
(	沈: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonatha	n; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa;
E	Fron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; L	ucas Smalldon; Rose Li Central Account; Dana Carluccio;
(	Chen, Helen Q.	
S	Subject: ACTIV-2 Writing Team and mAb Steering Committ	ee Joint Meeting - Protocol Update
١	When: Wednesday, May 27, 2020 1:00 PM-2:00 PM (UTC-0	)5:00) Eastern Time (US & Canada).
١	Where: b6	
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Dear ACTIV-2 Writing Team and ACTIV mAb Steering Committee,

We are looking forward to this joint meeting tomorrow in which the ACTIV-2 team will share their progress on the mAb outpatient master protocol with the Steering Committee. The team will review the current thinking within the protocol. Then they would like to solicit feedback from the Steering Committee about a few remaining questions that could still alter the protocol structure.

Please find attached the materials for tomorrow:

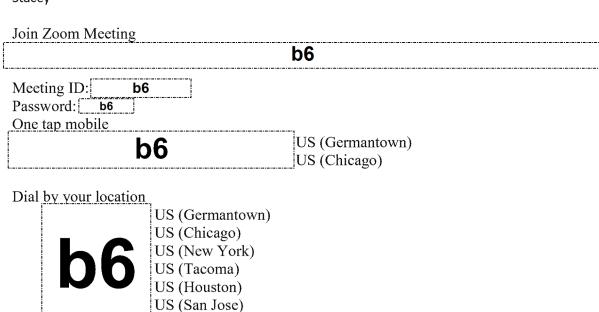
- 1. Meeting agenda
- 2. Current ACTIV-2 master protocol
- 3. Slides summarizing the current protocol

Please note that the stats team is still working to insert the final design of the Bayesian framework that will be used for agents beyond the first drug(s) into the trial for progression from Phase 2 to 3 within the study. This framework will not apply to the early entrants since prior learnings will be needed to inform the Bayesian model.

In addition, the team is waiting on some critical feedback from the FDA about how to address company feedback for a Phase 1(ish) safety/dose "run-in" study protocol that could be paired with the master protocol and potentially be overseen by ACTIV.

Thanks, Stacey

Meeting ID:



LUS (San Jose)

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Password: **b6**Find your local number: **b6** 

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	Carluccio	b6	; Chen, Helen Q. [qir	ngchen@deloitte.co	om]		
Subject:	Summary from AC	TIV-2 Writing Team and m.	Ab Steering Committee	Joint Meeting			
Attachments:	2020-05-27_TX-Cli	inical_WG_ACTIV-2_Writin	g Team_mAb_SC_Sumn	nary.pdf			

Dear ACTIV-2 Writing Team and ACTIV mAb Steering Committee,

Thank you so much for a very productive meeting with the ACTIV-2 team yesterday. I think we were able to make a lot of head way on the outstanding protocol decisions which helped the team refine further today on their call.

For your reference, please find attached the formal summary to the meeting. If you have additions or amendments, please contact me and I will make them.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] 5/29/2020 12:49:52 AM Sent: b6 Bascles, Lionel b6 Vincent, Mike Garner, Carlos To: Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry ; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers , Betsy **b6** Jickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura b6 ; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri b6 ; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wachtel, Jonathan [jwachtel@deloitte.com]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang] CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group 

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 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Criffield, Robin b6 ; Hamilton, Nancy b6 , Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth b6 | Mueller-Reichenstein, Petra | b6 |; Quadros, Nora | b6 |; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana

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; Heaton, Penny

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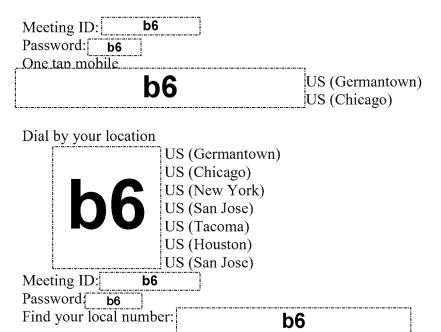
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John
	b6
Subject:	ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments:	Clinical Trial Capacity Working Group Meeting Agenda_05292020.pdf
Location:	b6
Start:	5/29/2020 1:00:00 PM
End:	5/29/2020 2:00:00 PM
Show Time As:	
Recurrence:	Weekly
	every Tuesday and Friday from 9:00 AM to 10:00 AM
Required	Garner, Carlos; Bascles, Lionel; Vincent, Mike; Payton, Manzine; Cohen, Myron; Corey, Larry; Davey, Victoria;
Attendees:	Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla
	Mike; Nayak, Seema (NIH/NIAID) [E]; Qashu, Felicia; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan,
	Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Mensah, George; Weinmann, Gail
Optional	Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Kublin MD, MPH, James; Ferguson, Sue; Kenny, Dermot;
Attendees:	Gonzalez, Nina; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein,
	Petra; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] ( b6 ); Zoe (NIH/NHLBI) Hill [C]
	b6 ; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E]
	<b>b6</b> Carluccio, Dana; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T];
	Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric;
	Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John
Colleagues -	Attaching the agenda for the call. Best, Karen
Concugues	readining the agenta for the can. Best, reafor
Dear Clinical	Trial Capacity WG members, This will extend our full working group calls through the end of May. We'll
	ed for further meetings at the end of the month. Many thanks for your participation! Karen
Join Zoom M	
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/29/2020 1:28:30 AM Sent: To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra b6 ; Eisner, Mark b6 Gottesdiener, Keith b6 ; Hughes, Eric b6 ; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [elkim@deloitte.com]; LaVange, Lisa b6 Levy, Elliot b6 Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras];

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b6 ; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  $(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs];\ Koroshetz,\ Walter and States are also supported by the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the proper$ (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy b6; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group CC: [/o=ExchangeLabs/ou=Exchange Administrative Group



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Required Attendees:

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Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E];

# Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] { Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner Optional Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas Attendees: (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; jennifer.j.palmer@pfizer.com; Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E] Dear ACTIV TX-Clinical WG, Please find attached the slides for tomorrow's meeting which contain the agenda. We will be using this meeting as last week to update on the progress of the master protocol groups and the mAb subteam from the Agent Prioritization group. Please let us know if there is anything else you feel the team needs to discuss. Thanks, Stacey Join Zoom Meeting b6 Meeting ID: Password: **b6** One tap mobile US (Germantown) **b6** US (Chicago) Dial by your location US (Germantown) US (Chicago) US (New York) US (San Jose)

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	Tolman, Brett [bto	man@deloit	te.com]; Alv	arez, Rö <u>sa [</u> i	osalvarez@	deloitte.co	m]; Gonzalez,	Nina	
	[ningonzalez@delc	oitte.com]; D	ana Carluccio	o [	b6		; Rose Li	Central Acco	ount
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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E];

# Optional Attendees:

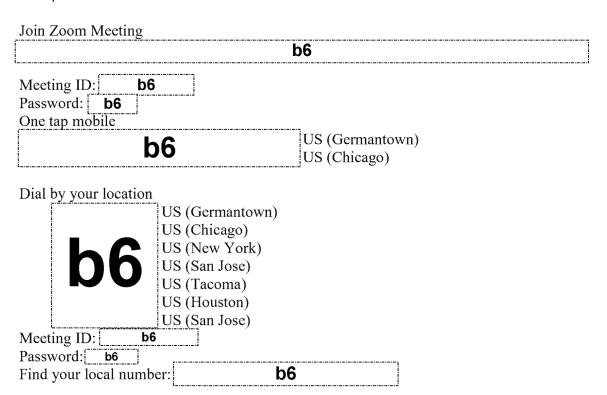
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Please let us know if there is anything else you feel the team needs to discuss.

Thanks, Stacey



From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]						
Sent:	5/29/2020 1:31:49 AM						
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CC:	Chen, Helen Q. b6 ; Demarcus b6 Tountas, Karen (FNIH) [T]						
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan						
	[jwachtel@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Salathin, Carla						
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Subject:	ACTIV-3 Writing Team and mAb Steering Committee Joint Meeting						
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Attendees:

Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Judy Currier; Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Lisa LaVange; Karen Lynn Price; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER)

Optional

Chen, Helen Q.; Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Salathin, Carla

Attendees:

Stacey Adam is inviting you to a scheduled Zoom meeting.

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Subject:	ACTIV-3 Writing Team and mAb Steering Committee Joint Meeting									
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Dear mAb Steering Committee and ACTIV-3 Writing Team,

Attendees:

Carla; Rose Li Central Account; Lucas Smalldon; Dana Carluccio; Bagiella, Emilia

Please find attached the agenda for tomorrow. The ACTIV-3 team is diligently working to incorporate the feedback from today into the latest version of the protocol outline. Once they circulate this latest version I will send to this group tomorrow for review.

Stacey Join Zoom Meeting b6 Meeting ID: b6 Password: **b6** One tap mobile US (Chicago) b6 US (New York) Dial by your location US (Chicago) US (New York) US (Germantown) US (Tacoma) US (Houston) US (San Jose) US (San Jose) Meeting ID: **b6** Password: **b6** Find your local number: b6

Thanks,

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	[jwachtel@deloitte.	e.com]; Elizabeth Kim [elkim@de	eloitte.com]; Pa	rker, Ashley (NIH/OD) [E]				
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Dear ACTIV-2 Writing Team,

Thank you all for a very productive meeting. I think we are making good head way on the protocol. Looking forward to sharing it with the companies and FDA next week for feedback.

Please find the notes from the meeting today. If you have any additions or amendments, let us know. In addition, please find the summary of the joint meeting with the mAb Steering Committee from yesterday. Take note of the minimal data that FDA mentions for entering Phase 2. I thought John's take was helpful.

Thanks, Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/29/2020 3:41:29 AM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes ]; LaVange, Lisa M | b6 ; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Karen Lynn Price ;; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group Bugin, Kevin (FDA/CDER) Bugin, Kevin (FDA/CDER) Bugin, Kevin (FDA/CDER) Bugin, Kevin (FDA/CDER) Bugin, Kevin (FDA/CDER) Bugin, Kevin (FDA/CDER) Bugin, Kevin (FDA/CDER) Bugin, Kevin (FDA/CDER) Bugin, Kevin (FDA/CDER) Bugin, Bugin, Kevin (FDA/CDER) Bugin, Bugin, Kevin (FDA/CDER) Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, Bugin, (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda] Demarcus Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative CC: Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Elizabeth Kim [elkim@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Chen, Helen Q. [qingchen@deloitte.com]; Salathin, Carla Subject: **ACTIV** mAb Steering Committee Meeting ACTIV_TX-Clinical_mAb Steering Committee Meeting_20200529.pdf Attachments: Location: b6 Start: 5/29/2020 6:00:00 PM 5/29/2020 7:00:00 PM End: Show Time As: Tentative Required Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E]; Attendees: Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER) Optional Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Attendees: Salathin, Carla Dear mAb Steering Committee, Please find attached the proposed agenda and slides for tomorrow. Please let us know if we need to add anything else to the agenda.

Thanks, Stacev

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

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To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]

CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]

Subject: FW: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)

Attachments: BIO_Dr Collins Keynote Invite.pdf

Is this good enough? Seems like they ought to try a little harder.

From: Allen-Gifford, Patrice (NIH/OD) [I	E] [	b6					
<b>Sent:</b> Friday, May 29, 2020 10:16 AM	·						
To: Collins, Francis (NIH/OD) [E]	b6						
Cc: Burklow, John (NIH/OD) [E]	b6	; Wood, Gretchen (NIH/OD) [E]	b6				
McManus, Ayanna (NIH/OD) [E]	b6	Twyman, Leslie (NIH/OD) [E]	,	b6			
Coley, Gwendolyn (NIH/OD) [C]	b6	}					
Subject: FW: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)							

FC, we asked BIO to make the panel in which they invited you to participate more inclusive. Below is the result—not sure if this one addition=inclusivity.

From: Sarah Arth	b6						
Sent: Friday, May 29, 2	020 9:52 AM						
To: Allen-Gifford, Patri	ce (NIH/OD) [E	] < b6	; Phyllis	Arthur	b6	 }	
Cc: NIH Director Invitat	ions < <u>NIHDire</u> c	ctorInvitations@nih.go	<u> </u>	\			
Subject: RE: [-EXTERNA	AL-] Invitation t	o speak at BIO Virtual	International Conv	ention (3909	956)		

Patrice,

My apologies for the delayed response. Below is the updated panel. We are pleased with the representation and hope that Dr. Collins can join us. Please do let me know.

# Leveraging Platforms and Partnerships to Develop COVID-19 Vaccines in Record Time Tuesday, June 9, 11:30 AM – 12:30 PM PT

As numerous vaccines move through clinical development there are important issues that need to be addressed. How will companies and partners conduct global clinical trials? What are the key scientific issues that must be addressed to vaccinate millions of people worldwide? This panel will discuss the complex path to clinical trials, the impact of the evolving science on their development and share their thoughts on how collaboration will bring life-saving vaccines to the world.

Moderator: Mark McClellan, MD, Director, Duke Margolis Center for Health Policy

### Panelists:

- Gregory Glenn, MD, Chief Scientific Officer, Novavax
- Margaret Hamburg, MD, Foreign Secretary, National Academy of Medicine
- Peter Marks, MD, PhD, Director, Center for Biologics Evaluation and Research, United States Food and Drug Administration
- Gary Nabel, MD. PhD, Chief Scientific Officer, Sanofi (invited)

Sarah S. Arth, CAE Vice President, Education Biotechnology Innovation Organization O – b6 M –
From: Allen-Gifford, Patrice (NIH/OD) [E] b6  Sent: Friday, May 29, 2020 9:33 AM  To: Sarah Arth b6; Phyllis Arthur b6  Cc: NIH Director Invitations < NIHDirectorInvitations@nih.gov >  Subject: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)  Importance: High
Good day,
I am writing to you in follow up to Mr. Greenwood's message to me earlier this week. Do you have any further information that we may share with Dr. Collins?
With kind regards,
Patrice Allen-Gifford  Director  Executive Secretariat  National Institutes of Health  One Center Drive, B1-46  Bethesda, MD 20892  Tel:  Cell  b6
From: James C. Greenwood b6
Sent: Sunday, May 24, 2020 6:10 PM
To: Allen-Gifford, Patrice (NIH/OD) [E] b6  Cc: Sarah Arth b6 Twyman, Leslie (NIH/OD) [E] b6 >; NIH Director Invitations
<nihdirectorinvitations@nih.gov>; Phyllis Arthur b6 &gt;</nihdirectorinvitations@nih.gov>
Subject: RE: [-EXTERNAL-] FW: For FC Decision: Invitation to speak at BIO Virtual International Convention (390956)
Thank you, Patrice. I believe we have already managed to do this. My staff will respond to you.
From: Allen-Gifford, Patrice (NIH/OD) [E] b6
<b>Sent:</b> Sunday, May 24, 2020 5:56 PM <b>To:</b> James C. Greenwood
To: James C. Greenwood
< <u>NIHDirectorInvitations@nih.gov</u> >
Subject: Invitation to speak at BIO Virtual International Convention

• Paul Stoffels, MD, Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson

#### Dear Mr. Greenwood,

Dr. Collins received your invitation to speak as part of a three-part plenary at BIO's virtual convention on June 11 and has asked me to thank you for inviting him to participate in this important and timely discussion on Leveraging Platforms and Partnership to Develop COVID-19 vaccines. As you may know, Dr. Collins is very committed and devoting enormous time to just such a unique effort, known as ACTIV. He would like to contribute to the BIO panel discussion, however, he has also committed to inclusiveness and ensuring a level playing field in speaking opportunities; he issued a <a href="statement">statement</a> outlining his commitment last year. The panel proposed in your invitation letter does not reflect that diversity. May we ask if there is a possibility of creating a more inclusive panel of speakers? Thank you again for thinking of Dr. Collins and NIH.

Most respectfully,

## Patrice Allen-Gifford

Director
Executive Secretariat
National Institutes of Health
Cell: **b6** 

From: James C. Greenwood		
<b>Sent:</b> Thursday, May 14, 202	0 5:59 PM	
To: Collins, Francis (NIH/OD)	[E] <b>b6</b>	>
Cc: b6		

Subject: Dr. Collins - Invitation to speak at BIO Virtual International Convention

# Dear Francis,

I hope this email finds you well. Thanks for your grand leadership in this awful time. Given the current environment, we have taken our annual BIO International Convention to a digital format this year. COVID-19 will be at the forefront of the content that we are planning for the event and we would like to invite you to participate in our three-part plenary, *A Way Forward: Winning the War on COVID through Vaccines*. I have attached a formal invite with complete session details. The session will take place on Tuesday, June 9 from 2:30 PM – 3:30 PM ET virtually. We hope that you can join us.

I look forward to your response.

All the best,

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL] Sent: 5/29/2020 2:39:36 PM To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd] Re: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956) Subject: Follow up Flag: No it is not adequate. In fact it is insulting. From: Francis Collins **Date:** Friday, May 29, 2020 at 10:36 AM To: "Wolinetz, Carrie (NIH/OD) [E]" **b6** Cc: "Tabak, Lawrence (NIH/OD) [E]" Subject: FW: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956) Is this good enough? Seems like they ought to try a little harder. b6 From: Allen-Gifford, Patrice (NIH/OD) [E] **Sent:** Friday, May 29, 2020 10:16 AM To: Collins, Francis (NIH/OD) [E] **b6** Wood, Gretchen (NIH/OD) [E] Cc: Burklow, John (NIH/OD) [E] McManus, Ayanna (NIH/OD) [E] Twyman, Leslie (NIH/OD) [E] Coley, Gwendolyn (NIH/OD) [C]: b6 Subject: FW: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956) FC, we asked BIO to make the panel in which they invited you to participate more inclusive. Below is the result—not sure if this one addition=inclusivity. From: Sarah Arth Sent: Friday, May 29, 2020 9:52 AM To: Allen-Gifford, Patrice (NIH/OD) [E] ; Phyllis Arthur Cc: NIH Director Invitations < NIHDirectorInvitations@nih.gov> Subject: RE: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956) Patrice,

My apologies for the delayed response. Below is the updated panel. We are pleased with the representation and hope that Dr. Collins can join us. Please do let me know.

# Leveraging Platforms and Partnerships to Develop COVID-19 Vaccines in Record Time Tuesday, June 9, 11:30 AM - 12:30 PM PT

As numerous vaccines move through clinical development there are important issues that need to be addressed. How will companies and partners conduct global clinical trials? What are the key scientific issues that must be addressed to vaccinate millions of people worldwide? This panel will discuss the complex path to clinical trials, the impact of the evolving science on their development and share their thoughts on how collaboration will bring life-saving vaccines to the world.

Moderator: Mark McClellan, MD, Director, Duke Margolis Center for Health Policy

# Panelists:

- Gregory Glenn, MD, Chief Scientific Officer, Novavax
- Margaret Hamburg, MD, Foreign Secretary, National Academy of Medicine
- Peter Marks, MD, PhD, Director, Center for Biologics Evaluation and Research, United States Food and Drug Administration
- Gary Nabel, MD. PhD, Chief Scientific Officer, Sanofi (invited)
- Paul Stoffels, MD, Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson

Sarah S. Ar	th, CAE
Vice Preside	nt, Education
Biotechnolo	gy Innovation Organization
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M - <b>b</b>	0

Sent: Sunday, May 24, 2020 6:10 PM To: Allen-Gifford, Patrice (NIH/OD) [E]

b6

<NIHDirectorInvitations@nih.gov>; Phyllis Arthur

Cc: Sarah Arth

From: Allen-Gifford,	Patrice (N	IIH/OD) [E]	b6					
Sent: Friday, May 29,	2020 9:3	33 AM						
To: Sarah Arth	b6	; Phyllis Arthur	b6					
Cc: NIH Director Invit	ations < 🏻	IIHDirectorInvitations	@nih.gov>					
Subject: [-EXTERNAL-	-] Invitati	on to speak at BIO Vir	tual Internat	ional Cor	vention (	390956)		
Importance: High								
Good day,								
I am writing to you in	follow u	p to Mr. Greenwood'	s message to	me earli	er this we	ek. Do yo	u have any fi	urther
information that we	may shar	e with Dr. Collins?						
With kind regards,								
Patrice Allen-Gifford								
Patrice Allen-Gifford Director								
Patrice Allen-Gifford Director Executive Secretariat								
Patrice Allen-Gifford Director Executive Secretariat National Institutes of	Health							
Patrice Allen-Gifford Director Executive Secretariat National Institutes of One Center Drive, B1	Health -46							
Patrice Allen-Gifford Director Executive Secretariat National Institutes of One Center Drive, B1 Bethesda, MD 20892	Health -46							
Patrice Allen-Gifford Director Executive Secretariat National Institutes of One Center Drive, B1	Health -46							
Patrice Allen-Gifford Director Executive Secretariat National Institutes of One Center Drive, B1 Bethesda, MD 20892	Health -46							
Patrice Allen-Gifford Director Executive Secretariat National Institutes of One Center Drive, B1 Bethesda, MD 20892 Tel	Health -46							

Thank you, Patrice. I believe we have already managed to do this. My staff will respond to you.

b6 Subject: RE: [-EXTERNAL-] FW: For FC Decision: Invitation to speak at BIO Virtual International Convention (390956)

b6

; NIH Director Invitations

b6

Twyman, Leslie (NIH/OD) [E]

From: Allen-Gifford, P	atrice (NIH/OD) [E]	b6		
Sent: Sunday, May 24	, 2020 5:56 PM		·	
To: James C. Greenwo	ood <b>b6</b>	<u> </u>		
Cc: b6	Twyman, I	eslie (NIH/OD) [E]	b6	; NIH Director Invitations
< NIHDirectorInvitatio	ns@nih.gov>	<b>L</b>		
Subject: Invitation to	speak at BIO Virtual I	nternational Conventi	on	

Dear Mr. Greenwood,

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Most respectfully,

### Patrice Allen-Gifford

Director
Executive Secretariat
National Institutes of Health
Cell: **b6** 

From: James C. Greenwood	b6		
Sent: Thursday, May 14, 202	0 5:59 PM		
To: Collins, Francis (NIH/OD)	[E] <b>b6</b>		
Cc: sara.radcliffe.7	b6	<u>-</u>	
Subject: Dr. Collins - Invitation	on to speak at BIO	Virtual International Co	nvention

Dear Francis,

I hope this email finds you well. Thanks for your grand leadership in this awful time. Given the current environment, we have taken our annual BIO International Convention to a digital format this year. COVID-19 will be at the forefront of the content that we are planning for the event and we would like to invite you to participate in our three-part plenary, *A Way Forward: Winning the War on COVID through Vaccines*. I have attached a formal invite with complete session details. The session will take place on Tuesday, June 9 from 2:30 PM – 3:30 PM ET virtually. We hope that you can join us.

I look forward to your response.

All the best,

From: Wolinetz, Carrie (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1C655040D47346C7B04D7BC11A403ECB-WOLINETZCD]

**Sent**: 5/29/2020 2:55:30 PM

CC:

Subject:

To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf] Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]

RE: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)

Seems pretty paltry to me, too. I think you should just say no. Alternatively, would Hilary Marston be an appropriate substitute? That way you could help them out with gender balance, take something off your plate, and maintain your "no manel" principle in one fell swoop...

From: Collins, Francis (NIH/OD) [E] b6

Sent: Friday, May 29, 2020 10:37 AM

To: Wolinetz, Carrie (NIH/OD) [E] b6

Cc: Tabak, Lawrence (NIH/OD) [E] Subject: FW: [-EXTERNAL-] Invitation to speak at BIO Virtual International Convention (390956)

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To: Collins, Francis (NIH/OD) [E]	b6				
Cc: Burklow, John (NIH/OD) [E]	b6	Wood, Gretchen (NIH/OD) [E]	b6	<u> </u>	
McManus, Ayanna (NIH/OD) [E	b6	Twyman, Leslie (NIH/OD) [E]		b6	
Coley, Gwendolyn (NIH/OD) [C]	DO				
Subject: FW: [-EXTERNAL-] Invitation to	speak at BIO	Virtual International Convention (390956)	)		

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<b>Sent:</b> Friday, May 29, 2020 9:52 AM				
To: Allen-Gifford, Patrice (NIH/OD) [E]	b6	; Phyllis Arthur	b6	
Cc: NIH Director Invitations < NIHDirectorInvitations	ations@nih.gov>			
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development and share their thoughts on how collaboration will bring life-saving vaccines to the world.

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Sarah S. Arth, CAE
Vice President, Education
Biotechnology Innovation Organization
O | b6

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Sent: Friday, May 2	9, 2020 9:3	33 AM							
To: Sarah Arth	b6	Phyllis Arthur	b6	}					
		NHDirectorInvitations@							
Subject: [-EXTERNA	L-] Invitati	on to speak at BIO Virt	ual Intern	ational (	Conventi	on (390	956)		
Importance: High									
Good day,									
I am writing to you	in follow u	p to Mr. Greenwood's	message 1	to me ea	arlier this	s week.	Do you h	ave any fu	rther
information that we	e may shar	e with Dr. Collins?							
With kind regards,									
000 - v 2 00 88	<b>S</b>								
Patrice Allen-Giffor	a								
Director	,								
Executive Secretaria									
National Institutes									
One Center Drive, E									
Bethesda, MD 2089	2								
Tel: h6									
Cell[ DO	<u> </u>								

From: James C. Greenwo	ood <b>b6</b>			
Sent: Sunday, May 24, 2	020 6:10 PM			
To: Allen-Gifford, Patrice	e (NIH/OD) [E]	b6		
Cc: Sarah Arth b6	; Twyman, l	eslie (NIH/OD) [E]	b6	; NIH Director Invitations
< NIHDirector Invitations	@nih.gov>; Phyllis A	Arthur <b>b</b> 6		·
Subject: RF: [-FXTFRNAL	-1 FW: For FC Decis	ion: Invitation to sne	ak at BIO Virtual I	nternational Convention (390956)

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To: James C. Greenwood	b6			
Cc: b6	; , ,	eslie (NIH/OD) [E]	b6	; NIH Director Invitations
<nihdirectorinvitations@nih.g< td=""><td><u>ov</u>&gt;</td><td>· · · · · · · · · · · · · · · · · · ·</td><td></td><td></td></nihdirectorinvitations@nih.g<>	<u>ov</u> >	· · · · · · · · · · · · · · · · · · ·		
<b>Subject:</b> Invitation to speak at	BIO Virtual In	ternational Conventior	1	

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Director
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To: Collins, Francis (NIH/OD	) [E] <b>b6</b>
Cc: sara.radcliffe.7	b6

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All the best,

From: Wachtel, Jonathan [jwachtel@DELOITTE.com] 5/29/2020 3:09:52 PM Sent: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Garner, Carlos ; Bascles, Lionel b6 ; Vincent, Mike ; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry ; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy ; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura ; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri j; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang] CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Kublin MD, MPH, James ; Ferguson, Sue **b6** ]; Kenny, Dermot Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Criffield, Robin **b6**; Hamilton, Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth ; Mueller-Reichenstein, Petra ; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [marganderson@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana Heaton, Penny [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose b6 ; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy ; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative

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000000000000000000000000000000000000000	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine
	(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric  b6 ; Jansen, Kathrin b6 ; Lowy, Douglas (NCI)
	<b>b6</b> ; Jansen, Kathrin <b>b6</b> ; Lowy, Douglas (NCI)
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John
	b6
Subject:	RE: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Team-	
As a foll	ow-up to today's meeting/dashboard demo, please email me any additional feedback. I will ensure it gets back
to Kevin	and his team for incorporation into the tool.
Addition	nally, I am including the list of Networks which have submitted their site rosters to date. If you have any
connect	cions to missing Networks, feel free to send them a nudge or reminder to submit their roster so we can enrich
our geo	tracking dashboard.
•	ACTG
•	ARLG
•	PETAL
•	ChiLDReN
•	Clinical Trials in Organ Transplantation
	DILIN
	GpCRC
	GRADE
	HFN
	IDCRC
	iMALT
	LaRed
	MSC ARDS NASH CRN
	NEPTUNE
	PreCISE
	PTN
	TIN
	REPRIVE
•	USDRN
Best,	
Jonatha	n Wachtel
Deloitte	Consulting LLP
Tel/Direc	tt: i <b>b6</b> ] oitte.com
Orig	ginal Appointment
_	ountas, Karen (FNIH) [T] <b>b6</b>
Sent: Fr	iday, May 8, 2020 1:10 PM

**To:** Tountas, Karen (FNIH) [T]; Garner, Carlos; Bascles, Lionel; Vincent, Mike; Payton, Manizhe (NIH/NIAID) [E]; Cohen, Myron; Corey, Larry; Victoria Davey; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E];

GADB0000003327

Goff, David (NIH/NHLBI) [E]; Kurilla, Michael (NIH/NCATS) [E]; Nayak, Seema (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Mensah, George (NIH/NHLBI) [E]; Weinmann, Gail (NIH/NHLBI) [E]

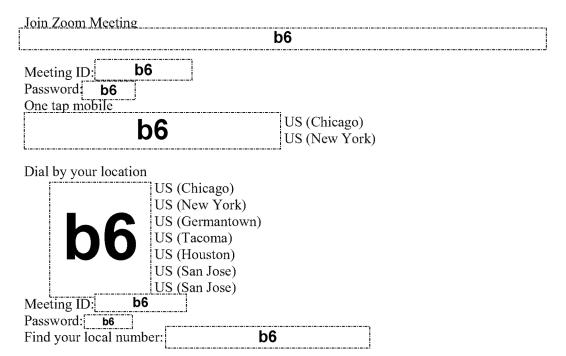
Cc: Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Kublin MD, MPH, James; Ferguson, Sue; Kenny, Dermot; Gonzalez, Nina; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein, Petra; Quadros, Nora; Katz, Rebecca (NIH/NCATS) [E]; Hill, Zoe (NIH/NHLBI) [C]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Parker, Ashley (NIH/OD) [E]; Carluccio, Dana; Heaton, Penny; James, Stephanie (FNIH) [T]; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Tuvesson, Nancy; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting

When: Friday, May 29, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada). Where: https://fnih.zoom.us/j/95092792940?pwd=N0xKLzJodEd1ZjZFVmNibDVKQ0hXQT09

Colleagues – Attaching the agenda for the call. Best, Karen

Dear Clinical Trial Capacity WG members, This will extend our full working group calls through the end of May. We'll assess the need for further meetings at the end of the month. Many thanks for your participation! Karen



This message (including any attachments) contains confidential information intended for a specific individual and purpose, and is protected by law. If you are not the intended recipient, you should delete this message and any disclosure, copying, or distribution of this message, or the taking of any action based on it, by you is strictly prohibited.

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v.E.1

From:	Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent:	5/29/2020 5:07:37 PM
То:	lim Neaton <b>h6</b> lens Lundgren <b>b6</b> Fric Hughes
	b6 ; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina
	(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy
	(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves
	(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Judy Currier
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Bozzette, Sam
	(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; LaVange, Lisa M
	b6 ); Karen Lynn Price b6 ; Woodcock, Janet (FDA/CDER)
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Carlos O Garner
	b6 ; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Marks, Gilbert
	(OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Farley, John
	(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]
cc:	Chen, Helen Q. [qingchen@deloitte.com]; Demarcus <b>b6</b> Tountas, Karen (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan
	[jwachtel@deloitte.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Salathin, Carla
	b6
	<u> </u>
Subject:	ACTIV-3 Writing Team and mAb Steering Committee Joint Meeting
Location:	b6
	<u>i</u>
Start:	6/5/2020 3:30:00 PM
End:	6/5/2020 4:30:00 PM
Show Time As:	Tentative

Required Attendees:

Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Judy Currier; Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Lisa LaVange; Karen Lynn Price; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER)

Optional Chen, F

Attendees:

Chen, Helen Q.; Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Salathin, Carla

Stacey Adam is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting	
	b6
Meeting ID: <b>b6</b>	
Password: <b>b6</b>	
One tap mobile	
b6	US (Chicago) US (New York)
Dial by your location	
US (Chicago) US (New York) US (Germantown) US (Tacoma) US (Houston) US (San Jose) US (San Jose)	
Meeting ID: <b>b6</b>	
Password: b6	;
Find your local number:	h6

From: Prabha Fernandes b6 Sent: 5/29/2020 7:31:05 PM To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group b6 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; b6 Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group] ์(FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; b6 Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Rao, Srinivas' ; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; 'Tomas Cihlar' (USA)' Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group CC: (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; 'Hughes, Eric' ]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; 'Desrosiers, Betsy' ; 'Jansen, Kathrin' **b6** ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; 'Alvarez, Rosa Maria' [rosalvarez@deloitte.com]; 'Kim, Elizabeth' [elkim@deloitte.com]; 'Tolman, Brett' [btolman@deloitte.com];

	'Wachtel, Jonathan				b	6 Diamond	
	Michael	b6 'R	ose Li'	b6	; 'Dana Carlucc		
		6	; Lagos, Enriqu	e (NIH/NCATS) [E] [,	o=ExchangeLab	os/ou=Exchange	
	Administrative Grou	up (FYDIBOHF23S	PĎLT)/cn=Recipie	nts/cn=ae9041ab2	7204d83b06752	2f67a44b0d1-lagoses];	
	Jonson, Samantha (	NIH/NCATS) [E] [/	o=ExchangeLabs	ou=Exchange Adm	inistrative Grou	р	
	(FYDIBOHF23SPDLT	)/cn=Recipients/c	n=ce2f69369d65	4bef89b0d39b145	d69a7-jonsonsg	]; Burrus-Shaw, Cyndi	
	(NIH/OD) [E] [/o=Ex	changeLabs/ou=f	Exchange Admini	strative Group			
	(FYDIBOHF23SPDLT					'Rodriguez, Robin D'	
	b6	]; 'Dave Franko	owski'	b6	; 'Ba	ric, Toni C'	
	b6	i	wy, Douglas (NII	I/NCI) [E] [/o=Excha	ingeLabs/ou=Ex	change Administrative	
'	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint						
	(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group						
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood						
	[/o=ExchangeLabs/	•					
	•		:n=03d589f440d8	34691ac0a530e4ba	6ceb5-haigwoor	n.oh]; 'Stratton, Benjamin'	
	[bstratton@DELOIT	•					
Subject:	RE: ACTIV Preclinica	• • • • •	, -	•			
Attachments:	GC376 A vet feline i	nfectious periton	tis Anivvive .pdf;	GC376 JJ Viology 20	015-Kim-feline c	oronavirusl - Copy.pdf	

Hi Joe,

When we prioritize re-purposed drugs..

Should we should include vet products. Anvive has announced it data on SARS CoV2.. they have been developing the compound for feline infectious peritonitis. Protease inhibitor.

Oral product.

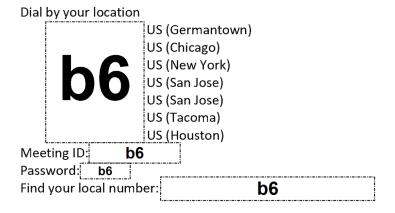
Selectivity index is great..

Attached FYI in case you have not seen.

Regards, Prabha

From: Menetski, Joseph		b6					
Sent: Friday, May 29, 202							
To:	b	6 b6		<u>i</u>	lild, Sheri (NIF	1/OD) [E]	
<u> </u>		b6				l	; Ottinger,
Elizabeth (NIH/NCATS [E	b6	;	Colvis, Christir	ne (NIH/NCAT	S) [E]		, 0
Hewitt, Judith (NIH/NIAII						b6	
	b6				hley (NIH/OD	) [E]	
	b6	Adams, Peter (OS/ASPR/BARDA)					
	b6		; Q	ashu, Felicia (	NIH/OD) [E]		
b6	Tomas Cihlar			b6			
(USA) b6	>		-				
Cc: Gadbois, Ellen (NIH/C	DD) [E] b	<b>)</b> 6	Hughes, Eric		b6	; Gonzalez,	Nina
<ningonzalez@deloitte.c< td=""><td>om&gt;; Cutillo, Chris</td><td>tine (NIH/NCA</td><td>ιTS) [Ε]</td><td>b6</td><td>&gt;; Simon, l</td><td>Dina (NIH/OD</td><td>) [C]</td></ningonzalez@deloitte.c<>	om>; Cutillo, Chris	tine (NIH/NCA	ιTS) [Ε]	b6	>; Simon, l	Dina (NIH/OD	) [C]
b6;	Wholley, David (FN	IIH) [T][	b6	; Austin, Chr	istopher (NIH	/NCATS) [E]	
b6	Melencio, Cheryl (	(FNIH) [T][	b6	; Colvis,	Christine (NIF	I/NCATS) [E]	
b6	: Desrosiers, Bet	svi	b6	<b>&gt;:</b>	lansen. Kathri	n	
b6	; Kurilla, Mich	ael (NIH/NCA	TS) [E	b6	; Lowy,	Douglas (NCI	)
<b>b6</b> ; Read,	Sarah (NIH/NIAID)	[E] <u>[</u>	b6	; Tountas, Ka	ren (FNIH) [T]	b6	j.
Santos, Michael (FNIH) [7	b6	; Adam, S	tacey (FNIH) [	T] b6	; Jam	es, Stephanie	(FNIH)
[T] <b>b6</b> ; A	Alvarez, Rosa Maria	a <rosalvarez@< td=""><td>deloitte.com</td><td>&gt;; Kim, Elizab</td><td>eth <elkim@d< td=""><td>deloitte.com&gt;</td><td>; Tolman,</td></elkim@d<></td></rosalvarez@<>	deloitte.com	>; Kim, Elizab	eth <elkim@d< td=""><td>deloitte.com&gt;</td><td>; Tolman,</td></elkim@d<>	deloitte.com>	; Tolman,

Brett <btolman@deloitte.com>; Wachtel, Jonathan <jwachtel@deloitte.com>; Prabhavathi Fernandes</jwachtel@deloitte.com></btolman@deloitte.com>							
b6		nd, Michael	b6		Rose Li		
b6	; Dana Carlı	L	b6			Enrique (NIH/NCATS) [E]	
b6	; Jonson, Samant	na (NIH/NCATS) [E]		b6	=:=:=:=:=:=:=:	rrus-Shaw, Cyndi	
(NIH/OD) [E]	b6	; Rodriguez, Robin D	! ! !	b6		Frankowski	
b		Baric, Toni C		·6		wy, Douglas (NIH/NCI) [E]	
b6	Florence, Clint (NIF	·	b6	j i	Nancy Haigwo	ood	
b6	i	n <bstratton@deloit< td=""><td>IE.com&gt;</td><td></td><td></td><th></th></bstratton@deloit<>	IE.com>				
Subject: RE: ACTIV Pre	eclinical working grou	p (Tuesday meeting)					
Dear Preclinical group	and attendees,						
Please find the minute	es to our meeting on	Wednesday. Let me k	now if yo	u have a	nny questions	or concerns with these.	
Thank you,							
Joe							
Original Appointm							
From: Menetski, Josep							
Sent: Tuesday, April 1					7	1 (may) 5 mm 2 1 1 1	
To:	b				Menetski, Jo	seph (FNIH) [T]; Hild,	
Sheri (NIH/OD) [E];		b6					
		<b>b6</b>					
i 	b6	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				DD) [E]; Collins, Francis	
(NIH/OD) [E];	b6				; Rao, Srinivas	; Qashu, Felicia (NIH/OD)	
[E]; Tomas Cihlar;		6	(USA	•	U (NICATE) [E]	Ciman Dina (NULL/OD)	
[C]; Wholley, David (F				-		; Simon, Dina (NIH/OD)	
	•					uglas (NCI); Read, Sarah	
		•	• -	•	,	James, Stephanie (FNIH)	
						des; Diamond, Michael;	
Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint							
(NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin							
Subject: ACTIV Preclinical working group (Tuesday meeting)							
When: Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).							
Where:		b6					
Changing time for pre	clinical WG						
Joseph Menetski is inviting you to a scheduled Zoom meeting.							
Join Zoom Meeting							
	b	6					
Meeting ID: <b>b6</b>							
Password: <b>b6</b>	i						
One tap mobile							
i _	C	US (Germantown)					
D	6	US (Chicago)					
<b>b</b>							



(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC] Sent: 5/29/2020 7:36:02 PM To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf] CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras] Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30 Yes, I will send it to Nina. From: Wholley, David (FNIH) [T] b6 Sent: Friday, May 29, 2020 3:33 PM To: Collins, Francis (NIH/OD) [E] b6 Cc: Adam, Stacey (FNIH) [T] ; Freire, Maria (FNIH) [T] ; Gonzalez, Nina b₆ <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E][ Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30 By copy to Nina Gonzalez, I am asking formally if that is OK. We are fine with that of course. Ashley and Maria are corresponding on a slide that might fit for #1. From: Collins, Francis (NIH/OD) [E] b6 Sent: Friday, May 29, 2020 3:30 PM To: Wholley, David (FNIH) [T] ; Freire, Maria (FNIH) [T] b6 Cc: Adam, Stacey (FNIH) [T] b6 ; Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30 Hi David, Sorry, had an e-mail crash and am just now seeing this – it's a good thing you didn't wait for me! The outline looks good, I'll wait for the Deloitte versions. I don't have a slide that fits #1. NHLBI (Amy Patterson) is working on things for me by COB on anticoagulants. If I need to harmonize, is Deloitte available this evening? FC From: Wholley, David (FNIH) [T] b6 Sent: Friday, May 29, 2020 1:59 PM To: Collins, Francis (NIH/OD) [E] b6 Cc: Adam, Stacey (FNIH) [T] b6 j; Freire, Maria (FNIH) [T] Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] [ Subject: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30 Francis:

Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

From:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a portfolio approach to addressing the dramatic health and economic
  challenges posed by the pandemic, with harmonized efforts that address both disease etiology and
  symptomology.
  - ACTIV Baricitinib (ACTT2, sponsored by NIAID) in progress
  - o ACTIV hiVIG (sponsored by NIAID) in progress
  - ACTIV-1 Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) (Phase III) ready to launch late June
  - ACTIV-2*— Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
  - ACTIV-3* Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
  - ACTIV-4 Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually,
     Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS "Master" Network) (Phase II/III) –
     projected launch late June
  - ACTIV-5 De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) similar design to the mAb protocols, networks/sites/agents in discussions now projected launch August (if needed; i.e. if agents are not incorporated into mAb protocols)
     * current priority
    - [for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
  - Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
  - Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
     [Key Criteria for Scoring (slide 15 from 5/20) can go to backup
  - Prioritization and Protocol Design: Who is Involved two-box slide containing names and affiliations of those involved in the Proritization and MP Subgroups (quality folks!)
  - ACTIV-1 Protocol for immunomodulators
    - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
    - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
    - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials
       = high POS
    - Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
    - Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
    - o Protocol is 80% complete
      - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
        - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)

- All three companies have written their sections of the protocols, which are being merged into the master design
- Working with OWS/BARDA on choice of CRO to run the trial; revised cost estimate = \$60 million
- "ACTIV-4" Protocol for anticoagulants
  - Need bullets from NHBLI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS "network of networks" with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Kara Carter b6 5/29/2020 7:40:04 PM Sent: To: Prabha Fernandes Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; ; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative <u>Group (FYDIBOHF23SPDLT)</u>/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Rao, Srinivas' ; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; 'Tomas Cihlar' (USA) CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; 'Hughes, Eric' ; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; 'Desrosiers, Betsy' b6 ; Kurilla, Michael (NIH/NCATS) [E] ; 'Jansen, Kathrin' [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; 'Alvarez, Rosa Maria'

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	[bstratton@DELOIT	TE.com]								
Subject:	RE: ACTIV Preclinica	l working group	(Tuesday meeti	ng)						
Attachments:	Ma et al 2020 BioRx	iv Boceprevir G	C-376 and calpai	n inhibitors II XII inh	ibit SARS-CoV-2 viral replic	ation by targeting				
	the viral main prote	ase.pdf								

Thanks Prabha. Here is the recent submission to BioRxiv from Ma et al with the data on SARS-CoV-2 of the compound.

Kara



# Kara Carter, PhD Executive Vice President Infectious Disease b6 (Mobile) b6 www.evotec.com

From: Prabha Fernande	es [	h6							
Sent: Friday, May 29, 2	·			į					
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To: 'Menetski, Joseph (				b6				<u></u>	
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Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

# [EXTERNAL]

Hi Joe,

When we prioritize re-purposed drugs..

Should we should include vet products. Anvive has announced it data on SARS CoV2.. they have been developing the compound for feline infectious peritonitis. Protease inhibitor.

Oral product.

Selectivity index is great..

Attached FYI in case you have not seen.

Regards, Prabha

From: Menetski, Joseph	ո (FNIH) [T] [	b6	]				
Sent: Friday, May 29, 2	020 3:25 PM						
То:		b6		Hild	, Sheri (NIH/C	DD) [E]	
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(USA) b6							1
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Brett <btolman@deloit< td=""><td>te.com&gt;; Wachte</td><td>el, Jonathan &lt;<u>i</u>w</td><td>vachtel@deloitt</td><td><u>e.com</u>&gt;; Prabhav</td><td>athi Fernand</td><td>es</td><td></td></btolman@deloit<>	te.com>; Wachte	el, Jonathan < <u>i</u> w	vachtel@deloitt	<u>e.com</u> >; Prabhav	athi Fernand	es	
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Dear Preclinical gro	up and attende	es,		
Please find the mine	utes to our mee	eting on Wednesday. Let me kno	w if vou have anv	questions or concerns with these.
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Thank you,				
Joe				
Original Annain	tmo om t			
Original Appoint From: Menetski, Jos				
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Sent: Tuesday, Apri To:	1 14, 2020 6:43	b6		enetski, Joseph (FNIH) [T]; Hild,
Sheri (NIH/OD) [E];		b6		
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		<b>b6</b>		
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(NIH/OD) [E];	b6	; Adams, Peter (OS	/ASPR/BARDA); Ra	ao, Srinivas; Qashu, Felicia (NIH/OD)
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(NIH/NCATS) [E]; De	esrosiers, Betsy	; Jansen, Kathrin; Kurilla, Michae	I (NIH/NCATS) [E];	Lowy, Douglas (NCI); Read, Sarah
(NIH/NIAID) [E]; Tou	untas, Karen (FN	NIH) [T]; Santos, Michael (FNIH) [	T]; Adam, Stacey (	(FNIH) [T]; James, Stephanie (FNIH)
[T]; Alvarez, Rosa M	laria; Kim, Elizal	oeth; Tolman, Brett; Wachtel, Jo	nathan; Prabhavat	thi Fernandes; Diamond, Michael;
Rose Li; Dana Carlu	ccio; Lagos, Enri	ique (NIH/NCATS) [E]; Jonson, Sa	mantha (NIH/NCA	ATS) [E]; Burrus-Shaw, Cyndi
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		group (Tuesday meeting)		
When: Wednesday,	May 27, 2020	10:00 AM-11:00 AM (UTC-05:00)	Eastern Time (US	& Canada).
Where		<b>b6</b>		
Changing time for p	reclinical WG			. <u></u>
changing time for p	recimical WO			
Joseph Menetski is	inviting you to a	a scheduled Zoom meeting.		
Join Zoom Meeting				
		b6		
Meeting ID:	06			
Password: b6				
One tap mobile				
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Dial by your location				
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	US (Tacoma)
	US (Houston)
Meeting ID: <b>b6</b>	
Password: b6	
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### STATEMENT OF CONFIDENTIALITY.

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Please find our information on data protection <u>here</u>.

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP] Sent: 5/29/2020 7:40:20 PM b6 Hild, Sheri (NIH/OD) [E] To: [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; b6 Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; ; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas ; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group <u>(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm];</u> Tomas Cihlar b6 (USA) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group CC: (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hughes, Eric ; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy ; Jansen, Kathrin **b6** ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [rosalvarez@deloitte.com]; Kim, Elizabeth [elkim@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Wachtel,

	Jonathan	[jwachtel@	@deloitte.com];	Prabhavathi Fernandes	b6	; Diamond, Michael
		b6	; Rose Li	b6	; Dana Carluccio	
		be	6		/NCATS) [E] [/o=ExchangeL	
					n=ae9041ab27204d83b067	
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			-	Exchange Administrativ	-	l Dadainan Dahin D
	(FADIROH	b6			a299b318030c31f6-shawcy	
	<u> </u>	b6		_	@roseliassociates.com]; Ba [E] [/o=ExchangeLabs/ou=I	
	Gratin (EV		· ·		9478bb17840c56902718a-l	
			**	ou=Exchange Administra		owyaj, Florence, Cliff
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	-			ministrative Group	o, co , ia, , , o 200, o iio, ciio	
	-	_	_		ac0a530e4ba6ceb5-haigwo	on.oh]; Stratton, Benjamin
	-	n@DELOIT			ŭ	, ,
Subject:	RE: ACTIV	Preclinica	l working group	(Tuesday meeting)		
Attachments:	2020-05-2	27_Preclin	ical_WG_Summ	ary_D1.docx		
This time wit	h the atta	chment.				
Subject: RE: A	ACTIV Pred	linical wo	orking group (T	uesday meeting)		
Dear Preclinic	al group a	and atten	dees,			
Please find th	e minutes	to our m	eeting on Wed	dnesday. Let me know	if you have any question	s or concerns with these.
Thank you,						
Joe						
Original A	ppointme	nt				
From: Menet			Tì			
Sent: Tuesday			-			
To:	,,		b6		: Menetski.	Joseph (FNIH) [T]; Hild,
Sheri (NIH/O	D) [E]				namanananananananananananananananananan	
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i <u></u>			b6		Parker, Ashlev (NIH	i /OD) [E]; Collins, Francis
(NIH/OD) [E]		b6		Adams, Peter (OS/A		as; Qashu, Felicia (NIH/OD
[E]; Tomas Cil	nlar:		b6		(USA)	as) quarray remota (rimi) ob
		/OD) [F]:			• •	E]; Simon, Dina (NIH/OD)
					Melencio, Cheryl (FNIH) [	
			· · · · · · · · · · · · · · · · · · ·			ouglas (NCI); Read, Sarah
			• •			]; James, Stephanie (FNIH)
						ndes; Diamond, Michael;
					nantha (NIH/NCATS) [E]; I	
	_				wy, Douglas (NIH/NCI) [E]	, Florence, Clint
		_	d; Stratton, Bei			
SUDJECT: ACID	v Preclinic	al Workir	ng group (Tuesa	gav meeting)		

When: Wednesday, Ma Where:	ay 27, 2020 10:00 AM-1	11:00 AM (UTC <b>b6</b>	-05:00) Eastern Time (US & Canada).					
Changing time for precl	Changing time for preclinical WG							
Joseph Menetski is invit	Joseph Menetski is inviting you to a scheduled Zoom meeting.							
Join Zoom Meeting								
	b6							
Meeting ID: b6 Password b6 One tap mobile								
be		JS (Germantow JS (Chicago)	/n)					
Dial by your location								
<b>b6</b>	S (Germantown) S (Chicago) S (New York) S (San Jose) S (San Jose) S (Tacoma) S (Houston)							
Password: <b>b6</b>			1					
Find your local number:	: <b>b6</b>							

From: Prabha Fernandes b6 5/29/2020 7:42:01 PM Sent: To: 'Kara Carter' ; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative] b6 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; b6 i; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Rao, Srinivas' ; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; 'Tomas Cihlar' (USA) CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; 'Hughes, Eric' Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; 'Desrosiers, Betsy' 'Jansen, Kathrin' Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; 'Alvarez, Rosa Maria'

[rosalvarez@d	eloitte.com];	'Kim, Elizabeth' [elkin	n@deloitte.com]; 'Tol	man, Brett' [btolman@del	oitte.com];						
'Wachtel, Jona			abhavathi Fernandes'		; 'Diamond						
Michael'	b6	; 'Rose Li'	b6	); 'Dana Carluccio'							
[	b6	; Lagos, En	rique (NIH/NCATS) [E	] [/o=ExchangeLabs/ou=Ex	change						
['] Administrative	Group (FYDI	BOHF23SPDLT)/cn=Re	cipients/cn=ae9041a	b27204d83b06752f67a44l	oOd1-lagoses];						
Jonson, Saman	tha (NIH/NC	ATS) [E] [/o=Exchange	Labs/ou=Exchange Ac	lministrative Group							
(FYDIBOHF23S	PDLT)/cn=Re	cipients/cn=ce2f6936	9d654bef89b0d39b14	15d69a7-jonsonsg]; Burrus	-Shaw, Cyndi						
(NIH/OD) [E] [/	(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group										
(FYDIBOHF23S	PDLT)/cn=Re	cipients/cn=5bbac95b	1f6e4514a299b3180	30c31f6-shawcy]; 'Rodrigu	ez, Robin D'						
b6	; 'Da	ve Frankowski'	b6	; 'Baric, Toni	C'						
	b6	; Lowy, Douglas	(NIH/NCI) [E] [/o=Exc	hangeLabs/ou=Exchange	Administrative						
Group (FYDIBC	HF23SPDLT),	cn=Recipients/cn=f1k	7b8fe4739478bb178	40c56902718a-lowyd]; Flo	orence, Clint						
(NIH/NIAID) [E	] [/o=Exchan	geLabs/ou=Exchange /	Administrative Group								
(FYDIBOHF23S	PDLT)/cn=Re	cipients/cn=5e032d0b	c8554e8787e844a77	73295fe-florencewc]; Nan	cy Haigwood						
[/o=ExchangeL	abs/ou=Exch	ange Administrative G	Group								
(FYDIBOHF23S	PDLT)/cn=Re	cipients/cn=03d589f4	40d84691ac0a530e4l	oa6ceb5-haigwoon.oh]; 'St	tratton, Benjamin'						
[bstratton@DE	LOITTE.com]										

Subject:

RE: ACTIV Preclinical working group (Tuesday meeting)

# Thx much Kara!

I just heard that it is being made and sold black market in China.

From: Kara Carter		b6							
Sent: Friday, May 2	9, 2020 3	:40 PM							
To: Prabha Fernand	des	b6		े; 'Menetski	, José	eph (FNIH) [T]'	b6	)	
		b6				; 'Hild, S	heri (NIH/OD	)) [E]'	
			b€						
<b>b6</b> ; 'Ba	ric, Ralph		6	; 'Ottinger, E	lizab	eth (NIH/NCA)	ΓS [E]'		
b6		>; 'Colvis, Chr	istine (NIH/I	NCATS) [E]'		b6	b; 'Hew	itt, Judith (N	H/NIAID)
[E] b6	, innumumumumumumumumumumumumumumumumumumu	, 'Deming, Da	mon (FDA/C	DER)'			b6		ļ
	b6		; 'Parker, <i>l</i>	Ashley (NIH/	OD) [	E]'[ b6	b6		
b6		; 'Adam	s, Peter (OS/	ASPR/BARD	A)'[	b6	} 'Ra	ao, Srinivas'	
< b6	;	'Qashu, Felic	ia (NIH/OD)	[E]'	b6	; 'To	omas Cihlar'		
		b6				(USA		b6	
Cc: 'Gadbois, Ellen						·	b6	; 'Gonzale	ez, Nina'
<ningonzalez@delo< td=""><td>oitte.com</td><td>; 'Cutillo, Chr</td><td>istine (NIH/i</td><td>VCATS) [E]' {</td><td></td><td>b6</td><td>'Simon,</td><td>Dina (NIH/O</td><td>D) [C]'</td></ningonzalez@delo<>	oitte.com	; 'Cutillo, Chr	istine (NIH/i	VCATS) [E]' {		b6	'Simon,	Dina (NIH/O	D) [C]'
<b>b6</b>	'Wh	olley, David (F	NIH) [T]'	b6		; 'Austin, Chr ; 'Colvis,	istopher (NII	H/NCATS) [E]	
NO .	; 'Me	elencio, Chery	/I (FNIH) [T]'	b6		; 'Colvis,	Christine (NI	H/NCATS) [E]	1
b6	; '	Desrosiers, Bo	etsy[	b6		j>; 'J	ansen, Kathr	in'	
b6		; 'Kurilla, Mi	chael (NIH/N	ICATS) [E]' 🛴		b6	; 'Lowy	, Douglas (NO	CI)'
b6	Read, Sar	ah (NIH/NIAII	) [E]'[	b6		]; 'Tountas, Ka	ren (FNIH) [T	]'	
b6	; 'Santo	s, Michael (Fl	VIH) [T]'	b6		'Adam, Stace	y (FNIH) [T]'[	b6	,
'James, Stephanie (	FNIH) [T]'	b6	; 'Alva						
<elkim@deloitte.co< td=""><td>m&gt;; 'Toln</td><td>nan, Brett' <b< td=""><td>tolman@del</td><td>loitte.com&gt;;</td><td>'Wac</td><td>htel, Jonathan</td><td>' <jwachtel@< td=""><td>deloitte.com</td><td>1&gt;;</td></jwachtel@<></td></b<></td></elkim@deloitte.co<>	m>; 'Toln	nan, Brett' <b< td=""><td>tolman@del</td><td>loitte.com&gt;;</td><td>'Wac</td><td>htel, Jonathan</td><td>' <jwachtel@< td=""><td>deloitte.com</td><td>1&gt;;</td></jwachtel@<></td></b<>	tolman@del	loitte.com>;	'Wac	htel, Jonathan	' <jwachtel@< td=""><td>deloitte.com</td><td>1&gt;;</td></jwachtel@<>	deloitte.com	1>;
'Prabhavathi Ferna	ndes'		o <b>6</b>	'Diam	,	C		; 'Ro	se Li'
b6		'Dana Car	<u></u>		b6	b6	; 'Lagos, E	Enrique (NIH/	NCATS)
[E]' b6	aJ	់; 'Jonson, Sai						Burrus-Shaw	, Cyndi
(NIH/OD) [E]'	b	6	; 'Rodrigue	ez, Robin D'		b6	'Dave I	Frankowski'	
i	บช		i'Baric, Ton	i C'		b6	'Low	y, Douglas (N	IH/NCI)
[E] b6	; '	Florence, Clin	t̄ (NIH/NIAID	) [E]'		b6 ;	'Nancy Haig	wood'	
b6		atton, Benjan							
Subject: RF: ACTIV	Preclinica	l working gro	un (Tuesday	meeting)					

Thanks Prabha. Here is the recent submission to BioRxiv from Ma et al with the data on SARS-CoV-2 of the compound.

Kara

evotec						
Kara Carter, PhD	)					
Executive Vice Pre	sident Infectious (Mobile)	Disease				
b6 www.evotec.com						
From: Prabha Ferr	nandes	b6	·····			
Sent: Friday, May	29, 2020 3:31 PM		i			
To: 'Menetski, Jose	eph (FNIH) [T]'			o6		
b6	'Hild, Sheri	(NIH/OD) [E]		b6		I
b6	; Ka	ara Carter		b6		
'Baric, Ralph'	b6	; 'Ottinger, Eli	zabeth (NIH/NCATS	S [E]	b6	; 'Colvis,
Christine (NIH/NC/	ATS) [E]'	b6	; 'Hewitt, Judith (	NIH/NIAID) [E]'	b	6 'Deming
Damon (FDA/CDEF			b6			<u>i</u>
	Parker, /		[E]' <u>L</u>		b6	
'Adams, Peter (OS,		b6	>; 'Rao, Srini		b6	'Qashu, Felicia
(NIH/OD) [E]'				j 'F	Pitt, Margaret	T ČÍV USARMY
<b>Cc:</b> 'Gadbois, Ellen	USA)'	b6	nunununun.	.!	L- 0	
Cc: 'Gadbois, Ellen	(NIH/OD) [E]'	b6	; 'Hughes, Eri	c' <u>[</u>	b6	;\; 'Gonzalez, Nina' Dina (NIH/OD) [C]'
<ningonzalez@del< td=""><td>oitte.com&gt;; 'Cutill</td><td>o, Christine (NIF</td><td>, Hughes, En H/NCATS) [E]'[</td><td>b6</td><td>j; 'Simon,</td><td>Dina (NIH/OD) [C]'</td></ningonzalez@del<>	oitte.com>; 'Cutill	o, Christine (NIF	, Hughes, En H/NCATS) [E]'[	b6	j; 'Simon,	Dina (NIH/OD) [C]'
D6	; 'Wholley, D	avid (FNIH) [1]'[	b6	; 'Austin, Chr	ristopher (NIH	
b6	i 'Melencio,	Cheryl (FNIH) [1	) b6	; 'Colvis,	Christine (NII	
b6 b6	Desrosi	ers, Betsy'	<b>b6</b> /NCATS) [E]'	5 -	Jansen, Kathri	
	JD-s-d Corela (NUII	ia, iviicnaei (iviH,	b6	b6		Douglas (NCI)'
<u> </u>	'Read, Sarah (NIH			i Tountas, Ka ''Adam, Stace	ren (FNIH) [T	
'lamos Stanbania	; 'Santos, Mich	be !'Al	<b>b6</b> Ivarez, Rosa Maria'			
b6			deloitte.com>; 'Wa			
'Prabhavathi Ferna	r	<b>b6</b>		, Michael'	b6	; 'Rose Li'
b6		na Carluccio"	<b>b6</b>	, whereact		nrique (NIH/NCATS)
[E]' b6		on, Samantha (N		b6		Burrus-Shaw, Cyndi
(NIH/OD) [E]!			uez. Robin D'			rankowski'

b6 ; 'Florence, Clint (NIH/NIAID) [E]' b6

; 'Stratton, Benjamin' < bstratton@DELOITTE.com>

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

# [EXTERNAL]

Hi Joe,

When we prioritize re-purposed drugs..

'Lowy, Douglas (NIH/NCI)

; 'Nancy Haigwood'

Should we should include vet products. Anvive has announced it data on SARS CoV2.. they have been developing the compound for feline infectious peritonitis. Protease inhibitor.

Oral product.

Selectivity index is great..

Attached FYI in case you have not seen.

Regards, Prabha

From: Menetski, Joseph	·	b6				
Sent: Friday, May 29, 2					· <b></b>	
To:		b6			Hild, Sheri (NI	H/OD) [E]
		b6				<u> </u>
b6		Baric, Ralph	***************************************			Ottinger :
Elizabeth (NIH/NCATS [	E] b6		; Colvis, Chri:		· · · · · · · · · · · · · · · · · · ·	b6
Hewitt, Judith (NIH/NIA	(ID) [L]	) <b>6</b>	Deming, Da	mon (FDA/C	DER)	b6 ;
	b6				r, Ashley (NIH/OI	D) [E]
	b6		Adam	s, Peter (OS	/ASPR/BARDA)	
b6	Rao, Sriniva	b6		Qashu, Feli	icia (NIH/OD) [E]	
b6	Rao, Sriniva ; Tomas Cihlar	b6		;	b6	
(USA) b6						
Cc: Gadbois, Ellen (NIH,	/OD) [E]	b6	; Hughes, Er	ic {	b6	; Gonzalez, Nina
<ningonzalez@deloitte< td=""><td>.com&gt;; Cutillo, Chr</td><td>istine (NIH/NC</td><td>ATS) [E] &lt;</td><td>b6</td><td>; Simon,</td><td>Dina (NIH/OD) [C]</td></ningonzalez@deloitte<>	.com>; Cutillo, Chr	istine (NIH/NC	ATS) [E] <	b6	; Simon,	Dina (NIH/OD) [C]
b6 >	; Wholley, David (F }; Melencio, Chery	NIH) [T]	b <b>6</b>	; Austin	, Christopher (NII	H/NCATS) [E]
b6	; Melencio, Chery	I (FNIH) [T] {	b6		lvis, Christine (NI	H/NCATS) [E]
<b>b6</b>	; Desrosiers, Be	etsy	b6		Jansen, Kathr	rin
b6	; Meiencio, Chery ; Desrosiers, Be >; Kurilla, Mic	hael (NIH/NC	ATS) [E] {	b6	>; Lowy	, Douglas (NCI)
<b>b6</b> }; Read	d, Sarah (NIH/NIAID	) [E]	b6	Tountag	s, Karen (FNIH) [T	[] <b>b6</b>
Santos, Michael (FNIH)	[T] <b>b6</b>	Adam,	Stacey (FNIF	l) [T]	<b>b6</b> ; Jan	nes, Stephanie (FNIH)
						deloitte.com>; Tolman,
Brett < btolman@deloit	te.com>; Wachtel,	Jonathan < jw	achtel@delo	itte.com>; I	Prabhavathi Fern	andes
b6   b6	; Diam	ond, Michael	b	6	; Rose Li	
b6	; Dana Car	luccio (	be	Ď	>; Lagos, I	Enrique (NIH/NCATS) [E]
b6	; Jonson, Saman	tha (NIH/NCA	TS) [E]	b6	; Bur	rus-Shaw, Cyndi
(NIH/OD) [E]	b6	; Rodriguez,	Robin D	b6	Dave F	- rankowski
b6	; Jonson, Saman <b>b6</b>	; Baric, Toni C		b6	Low	y, Douglas (NIH/NCI) [E]
h6	Florence, Clint (N	IH/NIAID) [E]	b6		; Nancy Haigwoo	od
DU	; Stratton, Benjam					

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group and attendees,

Please find the minutes to our meeting on Wednesday. Let me know if you have any questions or concerns with these.

Thank you,

Joe

----Original Appointment----

From: Menetski, Joseph (FNIH) [T] Sent: Tuesday, April 14, 2020 6:43 PM

то	3	Menetski, Joseph (FNIH) [T]; Hild,
Sheri (NIH/OD) [E];	b6	
	b6	
b6	Parker,	Ashley (NIH/OD) [E]; Collins, Francis
(NIH/OD) [E]; <u>b6</u>		; Rao, Srinivas; Qashu, Felicia (NIH/OD)
[E]; Tomas Cihlar; b	(00/1)	
Cc: Gadbois, Ellen (NIH/OD) [E]; Hughes, Eri		
[C]; Wholley, David (FNIH) [T]; Austin, Chris		
(NIH/NCATS) [E]; Desrosiers, Betsy; Jansen,		
(NIH/NIAID) [E]; Tountas, Karen (FNIH) [T];		
[T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tol		
Rose Li; Dana Carluccio; Lagos, Enrique (NII		
(NIH/OD) [E]; Rodriguez, Robin D; Dave Fran		NIH/NCI) [E]; Florence, Clint
(NIH/NIAID) [E]; Nancy Haigwood; Stratton,		
Subject: ACTIV Preclinical working group (T	·	(116.9.6. 1.)
When: Wednesday, May 27, 2020 10:00 AN		(US & Canada).
Where:	b6	
Changing time for preclinical WG		
Joseph Menetski is inviting you to a schedu	led Zoom meeting.	
Jain Zaam Maating		
Join Zoom Meeting <b>b</b> i	<u> </u>	<del></del>
Meeting ID: <b>b6</b>		
Password: <b>b6</b>		
One tap mobile		
	US (Germantown)	
<b>b6</b>	US (Chicago)	
<u> </u>	0 /	
Dial by your location		
US (Germantown)		
_ US (Chicago)		
US (New York)		
US (New York) US (San Jose) US (San Jose)		
US (San Jose)		
US (Tacoma)		
US (Houston)		
Meeting ID: <b>b6</b>		
Password: <b>b6</b>		
Find your local number be	<u>5</u>	

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Please find our information on data protection here.

From: Sent:	Gonzalez, Nina [ningonzalez@deloitte.com] 5/29/2020 7:45:38 PM							
To:	Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]							
CC:	Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Elsaid, Olivia							
Subject:	[oelsaid@deloitte.com]; Stratton, Benjamin [bstratton@DELOITTE.com]  RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30							
All –								
	available for any clide harmonization this evening itset let Olivia and I know what you need							
	available for any slide harmonization this evening – just let Olivia and I know what you need.							
Thanks,								
Nina								
Sent: Frida To: Wholle Cc: Adam, S [E] Subject: [E	e, Maria (FNIH) [T] b6  y, May 29, 2020 3:36 PM  y, David (FNIH) [T] b6  Stacey (FNIH) [T] b6  Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD)  b6  XT] RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30  end it to Nina.</ningonzalez@deloitte.com>							
	lley, David (FNIH) [T] <b>b6</b> y, May 29, 2020 3:33 PM							
	Francis (NIH/OD) [E]   b6							
•	Stacey (FNIH) [T] b6 ; Freire, Maria (FNIH) [T] ( b6 ; Gonzalez, Nina							
	ez@deloitte.com>; Parker, Ashley (NIH/OD) [E] <b>b6</b> : Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30							
	Nina Gonzalez, I am asking formally if that is OK. We are fine with that of course. Ashley and Maria are ling on a slide that might fit for #1.							
Sent: Frida To: Wholle Cc: Adam, S <ningonzal< td=""><td>ns, Francis (NIH/OD) [E] &lt; b6</td></ningonzal<>	ns, Francis (NIH/OD) [E] < b6							
Hi David,								

Sorry, had an e-mail crash and am just now seeing this – it's a good thing you didn't wait for me! The outline looks good, I'll wait for the Deloitte versions. I don't have a slide that fits #1. NHLBI (Amy Patterson) is working on things for me by COB on anticoagulants. If I need to harmonize, is Deloitte available this evening?

FC

From: Wholley, David (FNIH) [T]	b6	]				
<b>Sent:</b> Friday, May 29, 2020 1:59 PM						
To: Collins, Francis (NIH/OD) [E]	b6			·		<del></del>
Cc: Adam, Stacey (FNIH) [T] b6		Freire,	Maria (FNIH) [T]	] {	b6	; Gonzalez, Nina
<ningonzalez@deloitte.com>; Parker, As</ningonzalez@deloitte.com>	hley (	NIH/OD)	[E] <b>b</b>	o6		
Subject: Key messages re: immunomodu	lators	for slide	s for Moncef me	eeting to	morrow 5	/30

#### Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a portfolio approach to addressing the dramatic health and economic
  challenges posed by the pandemic, with harmonized efforts that address both disease etiology and
  symptomology.
  - o ACTIV Baricitinib (ACTT2, sponsored by NIAID) in progress
  - ACTIV hiVIG (sponsored by NIAID) in progress
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  - ACTIV-2*— Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
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     * current priority

[for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base

- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
   [Key Criteria for Scoring (slide 15 from 5/20) can go to backup
- Prioritization and Protocol Design: Who is Involved two-box slide containing names and affiliations of those involved in the Proritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
  - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)

- 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
- All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials
   = high POS
- Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
- Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
- o Protocol is 80% complete
  - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
    - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
  - All three companies have written their sections of the protocols, which are being merged into the master design
- Working with OWS/BARDA on choice of CRO to run the trial; revised cost estimate = \$60 million
- "ACTIV-4" Protocol for anticoagulants
  - Need bullets from NHBLI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS "network of networks" with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley Senior Vice-President, Research Partnerships <u>Foundation for</u> the National Institutes of Health

b6

mih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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v.E.1

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]

**Sent**: 5/29/2020 9:58:59 PM

To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Freire, Maria (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];

Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]

Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Attachments: Responses to Qs re AC Clinical Trial Strategy 052920 final fsc.docx

### Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note – has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

## Thanks, Francis

From: Wholley, David (FNIH) [T]	b6	>						
<b>Sent:</b> Friday, May 29, 2020 1:59	PΜ		_					
To: Collins, Francis (NIH/OD) [E]	b6							
Cc: Adam, Stacey (FNIH) [T]	b6	⊳; Freire,	Maria (FNIH) [T]	b6	ļ	Gonzalez, N	lina	
<ningonzalez@deloitte.com>; Pa</ningonzalez@deloitte.com>	irker, Ashley	(NIH/OD)	[E] b	6				
Subject: Key messages re: immu	nomodulator	s for slide	s for Moncef me	eting tomorr	ow 5/30			

#### Francis

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David Wholley Senior Vice-President, Research Partnerships Foundation for the National Institutes of Health



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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Stacey Adam (Basecamp) **b6**Sent: 5/29/2020 10:46:17 PM

To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

**Subject**: Stacey A. added you to a team in Basecamp (FNIH Research Partnerships)



# Stacey Adam added you to ACTIV - Clinical Trial Capacity WG in Basecamp

Join Stacey in Basecemp

If you have any questions, just email Stacey or reply to this message.

Here's what's happened so far...

# 30 other people are on this team from our team

Badhri Srinivasan, Carlos Garner, Cheryl Melencio, Christine Sizemore, David Goff, Deanna Garner, Elizabeth Desrosiers, Felicia Qashu, Gail Weinmann, George Mensah, James Dickens, Janet Woodcock, Jim Doroshow, Jonathan Wachtel, Karen Tountas, Kevin Bugin, Kevin Footer, Larry Corey, Laura Resnansky, Lionel Bascles, Lynn Marks, Michael Vincent, Mike Kurilla, Molly Klote, Myron Cohen, Payton Manizhe, Peter Stein, Seema Nayak, Vicky Davey, and Victoria Davey.

#### Docs & Files were added for reference

Clinical_Trial_Capacity_Working_Group_Meeting_12_Final.pdf
Clinical_Trial_Capacity_Working_Group_Meeting_10_Final.pdf
Clinical_Trial_Capacity_Working_Group_Meeting_9_Final.pdf
Copy of Innovations Matrix 14May.xlsx
Clinical_Trial_Capacity_Working_Group_Meeting 8_Summary_Final.pdf
03 ACTIV Clinical Trial CRO-SMO Survey #1 May 2020.docx
02 ACTIV Clinical Trial SITE Survey #1 APRIL 2020.docx
01 ACTIV Clinical Trial NETWORK Survey #1 APRIL 2020.docx
Network Inventory Master Spreadsheet 05122020.xlsx
Clinical_Trial_Capacity_Working_Group_Meeting 7_Summary_Final.pdf
+ 42 more items...

From:	Stacey Adam (Basecamp)	b6
Sent:	5/29/2020 10:46:41 PM	L

To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject: Stacey A. added you to a team in Basecamp (FNIH Research Partnerships)



# Stacey Adam added you to ACTIV - Therapeutics Clinical WG in Basecamp

Join Stacey in Basecemp

If you have any questions, just email Stacey or reply to this message.

# Here's what's happened so far...

# 35 other people are on this team from our team

Amanda Peppercorn, Ashley Parker, Carlos Garner, Cheryl Melencio, David Goff, Deanna Garner, Elizabeth Higgs, Elizabeth Kim, Elliott Levy, Eric Hughes, Felicia Qashu, Helen Q. Chen, Janet Woodcock, Joan Butterton, John Mellors, Judy Currier, Keith Gottesdiener, Kevin Bugin, Lisa LaVange, Lora Reineck, Lynn Marks, Mary Biggs, Michael Proschan, Mike Poole, Naimish Patel, Neil Aggarwal, Peter Stein, R. Angelo De Claro, Ruxandra Draghia-Akli, Sam Bozzette, Sandeep Menon, Sarah Wynne Read, Sylva Collins, Tim Buchman, and Timothy Burgess.

### Docs & Files were added for reference

ACTIV_Therapeutics-Clinical_ACTIV TX-Clinical Neutralizing mAb Master Protocol Steering Committee with PETAL Network Leads_20May2020_Key Takeaways.pdf
ACTIV_Therapeutics-Clinical_AP Sub-Group Meeting 14May2020_Key Takeaways.pdf
ACTIV Therapeutics Clinical MP Sub Group 15May2020_Meeting Agenda.pdf
2020-05-14_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting Summary.pdf
2020-05-14_TX-Clinical_WG_Meeting_Summary.pdf
ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 15May2020_Key Takeaways.pdf
ACTIV_Therapeutics-Clinical_AP Sub-Group Meeting 12May2020 Key Takeaways.pdf
ACTIV Therapeutics-Clinical_MP Subgroup_13May2020 Meeting Guide.pdf
ACTIV Therapeutics-Clinical Full Working Group_14May2020 Meeting Guide.pdf
2020-05-07_TX-Clinical_WG_Meeting_Summary.pdf
+ 127 more items...

Need help? Contact our support team and we'll get back to you in just a few minutes. 6e75 feb35 dea7 cf161 d98901

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC] Sent: 5/29/2020 10:49:02 PM To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf] Subject: Re: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30 ١ On May 29, 2020, at 6:44 PM, Collins, Francis (NIH/OD) [E] Yes, she is waiting to see the draft ppts and will advise on the strategy then. Sent from my iPhone On May 29, 2020, at 6:06 PM, Freire, Maria (FNIH) [T] Francis - have you had a chance to chat with Janet to coordinate messages? She is critical - in her lowkey way, she is able to carry a huge part of the load. Moncef knows she has a rock-solid reputation with industry folks. And, of course, she was the one who asked for the money. M. b6 On May 29, 2020, at 5:59 PM, Collins, Francis (NIH/OD) [E] Hi all, I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study. See what you think. I stand ready to look at ppts anytime this evening. One question about the immunomodulator trial that I noticed in Moncef's note - has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint? Thanks, Francis From: Wholley, David (FNIH) [T] 4 Sent: Friday, May 29, 2020 1:59 PM To: Collins, Francis (NIH/OD) [E] Cc: Adam, Stacey (FNIH) [T] b6 ; Freire, Maria (FNIH) [T] ; Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] Subject: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30 Francis:

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<Responses to Qs re AC Clinical Trial Strategy 052920 final fsc.docx>

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Stacey	
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From:

Sent:

To:

CC:

Gonzalez, Nina [ningonzalez@deloitte.com]

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Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

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Sent: 5/30/2020 1:01:39 AM

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CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

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Attachments: ACTIV Therapeutics 053020.pptx

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Deloitte Consulting LLP Tel/Direct: +1 202 748 6535

ningonzalez@deloitte.com | www.deloitte.com

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]

Sent: 5/30/2020 1:01:41 AM

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- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
b6

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

**Sent**: 5/30/2020 1:17:20 AM

To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Elsaid, Olivia

[oelsaid@deloitte.com]

Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30

Attachments: ACTIV Therapeutics_053020v1.pptx

Hi Francis,

I have pre-emptively modified slide 7 to fit the description below. Please let me know if this makes more sense.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer Research Partnerships

	, <u>\</u>		{
Direct:	b6	Mobile:	b6

From: Adam, Stacey (FNIH) [T] Sent: Friday, May 29, 2020 9:13 PM

To: Collins, Francis (NIH/OD) [E] b6 ; Gonzalez, Nina <ningonzalez@deloitte.com>

Cc: Wholley, David (FNIH) [T] b6 ; Freire, Maria (FNIH) [T] b6 ; Parker, Ashley

(NIH/OD) [E] b6 ; Elsaid, Olivia <oelsaid@deloitte.com>

Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi Francis,

Here is what I know specifically from conversations with the companies.

- We know that BMS has ongoing Investigator Initiated Studies (IISs) with Abatacept that are early Phase II. Data not public yet.
- We know that Janssen also has a few preliminary trials, which is why they were getting ready to launch a large Phase 2 RCT of their own before they signed on to ACTIV-1, when we approached them. They had taken their protocol all the way through FDA approval.
- The only one I am not sure of is Cenicriviroc. AbbVie/Allergan have hinted at an IIS, but I would need to confirm. This was one of the R&D Consortium molecules, so I think they had some data to get it on that list.

I could reach out to the companies to see if they will give us more details, but I don't know if we would have it be your meeting with Moncef.

We can soften the language to say 2 of the 3 have known existing or ongoing Phase II is COVID-19.

Please let me know if you'd like the slide modified.
Thanks, Stacey
Stacey J. Adam, PhD Director, Cancer Research Partnerships Direct: b6   Mobile: b6
From: Collins, Francis (NIH/OD) [E] b6  Sent: Friday, May 29, 2020 9:02 PM  To: Gonzalez, Nina <ningonzalez@deloitte.com> Cc: Adam, Stacey (FNIH) [T] b6 ; Wholley, David (FNIH) [T] b6 ; Freire, Maria (FNIH) [T] b6 ; Parker, Ashley (NIH/OD) [E] b6 ; Elsaid, Olivia <oelsaid@deloitte.com> Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30  Hi all,</oelsaid@deloitte.com></ningonzalez@deloitte.com>
Thanks, this is an excellent set, though to keep the discussions with Moncef concise, I've moved some of the slides to the Appendix. See current version. I will send this to Janet now too.
One question: when the immunomodulator slide 7 says this:
All 3 agents have initial Phase II data or are currently running company-sponsored Phase II trials
What does that mean? Phase II trials for what application?
Francis
From: Gonzalez, Nina <ningonzalez@deloitte.com>  Sent: Friday, May 29, 2020 8:37 PM  To: Collins, Francis (NIH/OD) [E] b6  Cc: Adam, Stacey (FNIH) [T] b6 &gt;; Wholley, David (FNIH) [T] b6 &gt;; Freire, Maria (FNIH) [T]  b6 &gt;; Parker, Ashley (NIH/OD) [E] b6 ; Elsaid, Olivia <oelsaid@deloitte.com>  Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30</oelsaid@deloitte.com></ningonzalez@deloitte.com>
Hi Francis,
See attached the latest version of the slides for the meeting tomorrow.
We'll be on standby for any edits you may have.
Thank you,
Nina

Nina Gonzalez

Deloitte Consulting LLP Tel/Direct: +1 202 748 6535

ningonzalez@deloitte.com | www.deloitte.com

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From: Collins, Francis (NIH/OD) [E]	b6			
<b>Sent:</b> Friday, May 29, 2020 8:32 PM				
To: Wholley, David (FNIH) [T] <b>b</b> 6	}			
Cc: Adam, Stacey (FNIH) [T] <b>66</b>	Freire, Maria (Fl	NIH) [T]	<b>b6</b> }; (	Gonzalez, Nina
<ningonzalez@deloitte.com>; Parker, Asl</ningonzalez@deloitte.com>	nley (NIH/OD) [E]	b6	<u>}</u>	
Subject: [EXT] RE: Key messages re: immu	unomodulators for slide	es for Moncef m	eeting tomorr	ow 5/30
Hoping these are coming to me soon, Janet tonight.	as I may want to do s	some editing	and then I w	anted to run them past
FC				
From: Wholley, David (FNIH) [T]	b6			
Sent: Friday, May 29, 2020 7:41 PM				
To: Collins, Francis (NIH/OD) [E]	b6			
Cc: Adam, Stacey (FNIH) [T] b6	Freire, Maria (Fl	NIH) [T]	b6 ; (	Gonzalez, Nina
<ningonzalez@deloitte.com>; Parker, Asl</ningonzalez@deloitte.com>	nley (NIH/OD) [E]	b6	; Freire, M	laria (FNIH) [T]
b6				
Subject: RE: Key messages re: immunomo	odulators for slides for	Moncef meeting	tomorrow 5/	30
Have seen and offered a few changes to t makes the changes.	the complete slide deck	c. They should b	e coming bacl	cto you as soon as Deloitte
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<b>Sent:</b> Friday, May 29, 2020 5:59 PM				
<b>To:</b> Wholley, David (FNIH) [T]	<u> </u>	ŗ		
Cc: Adam, Stacey (FNIH) [Т] <u>ь6</u> <ningonzalez@deloitte.com>; Parker, Asl</ningonzalez@deloitte.com>		NIH) [T] <b>b</b> 6	b6 ; (	Gonzalez, Nina
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See what you think. I stand ready to look at ppts anytime this evening.

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Cc: Adam, Stacey (FNIH) [T] b6	; Freire,	Maria (FNIH) [T]	b6 ; Gonzalez, Nina	
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Subject: Key messages re: immunomodu	lators for slide	es for Moncef meeting tor	morrow 5/30	

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     * current priority

[for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base

- Prioritization Process (v 2.0) for ACTIV: (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
   [Key Criteria for Scoring (slide 15 from 5/20) can go to backup
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  - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
  - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
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- o Protocol is 80% complete
  - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
    - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
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Sent: Fo:	5/30/2020 1:22:11 AM Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC:	Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Freire, Maria (FNIH) [T]
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	(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, Nina
	[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
	Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Freire, Maria (FNIH) [T]
	[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
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	z@deloitte.com>; Parker, Ashley (NIH/OD) [E] <b>b6</b> ; Freire, Maria (FNIH) [T]
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viany than	ks. I await the masterpiece.
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	Francis (NIH/OD) [E] b6
	tacey (FNIH) [T] <b>b6</b> Freire, Maria (FNIH) [T] <b>b6</b> ; Gonzalez, Nina
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ro: wholey	tacov (ENIH) [T] be Proire Maria (ENIH) [T] b6 Gonzalez Nina
cninganzala	, May 29, 2020 5:59 PM  , David (FNIH) [T] b6  tacey (FNIH) [T] b6; Freire, Maria (FNIH) [T] b6; Gonzalez, Nina  2@deloitte.com>; Parker, Ashley (NIH/OD) [E] b6
Suhiect: RF:	Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30
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Cc: Adam, Stacey (FNIH) [T]	DO ,	e, Maria (FNIH) [T] 🖣	b6	; Gonzalez, Nina
<ningonzalez@deloitte.com>; Par</ningonzalez@deloitte.com>	ker, Ashley (NIH/OI	) [E] <b>b6</b>		
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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/30/2020 1:23:02 AM To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d] CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Elsaid, Olivia [oelsaid@deloitte.com] RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30 Subject: Hi Francis, That is my understanding that they were in hospitalized moderately ill. Stacey Stacey J. Adam, PhD Director, Cancer Research Partnerships **b6** From: Collins, Francis (NIH/OD) [E] b6 **Sent:** Friday, May 29, 2020 9:21 PM To: Adam, Stacey (FNIH) [T] b6 Gonzalez, Nina <ningonzalez@deloitte.com> Freire, Maria (FNIH) [T] Parker, Ashley Cc: Wholley, David (FNIH) [T] b6 (NIH/OD) [E] Elsaid, Olivia <oelsaid@deloitte.com> Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30 Thanks, Stacey. I assume these Phase II trials were for hospitalized COVID-19 patients, right? From: Adam, Stacey (FNIH) [T] Sent: Friday, May 29, 2020 9:13 PM To: Collins, Francis (NIH/OD) [E] [... ; Gonzalez, Nina <<u>ningonzalez@deloitte.com</u>> ; Freire, Maria (FNIH) [T] Cc: Wholley, David (FNIH) [T] b6 ; Parker, Ashley Elsaid, Olivia <oelsaid@deloitte.com> (NIH/OD) [E] Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi Francis,

Here is what I know specifically from conversations with the companies.

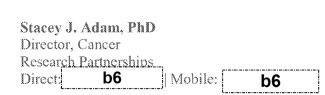
- We know that BMS has ongoing Investigator Initiated Studies (IISs) with Abatacept that are early Phase II. Data not public yet.
- We know that Janssen also has a few preliminary trials, which is why they were getting ready to launch a large Phase 2 RCT of their own before they signed on to ACTIV-1, when we approached them. They had taken their protocol all the way through FDA approval.

• The only one I am not sure of is Cenicriviroc. AbbVie/Allergan have hinted at an IIS, but I would need to confirm. This was one of the R&D Consortium molecules, so I think they had some data to get it on that list.

I could reach out to the companies to see if they will give us more details, but I don't know if we would have it be your meeting with Moncef.

We can soften the language to say 2 of the 3 have known existing or ongoing Phase II is COVID-19.

Please let me know if you'd like the slide modified.	
Thanks,	
Stacey	



From: Collins, Franci	s (NIH/OD) [E]	b6					
Sent: Friday, May 29	, 2020 9:02 PM						
To: Gonzalez, Nina <	ningonzalez@delc	itte.com>					
Cc: Adam, Stacey (FN	νιΗ) [Τ] <b>b6</b>	; Wholl	ey, David (FNIH) [ ⁻	T] <b>b</b>	6	; Freire, Maria (FNII	H) [T]
b6	; Parker, Ashley (N	IH/OD) [E]	b6	; Elsaid, Ol	livia < <u>oelsa</u> i	id@deloitte.com>	
Subject: RE: Key mes	ssages immunomo	dulators for slid	es for Moncef me	eting tomorr	ow 5/30		

Hi all,

Thanks, this is an excellent set, though to keep the discussions with Moncef concise, I've moved some of the slides to the Appendix. See current version. I will send this to Janet now too.

One question: when the immunomodulator slide 7 says this:

All 3 agents have initial Phase II data or are currently running company-sponsored Phase II trials

What does that mean? Phase II trials for what application?

Francis

b6	_] Freire, Maria (FNIH) [T]
Elsaid, Olivia < oelsa	id@deloitte.com>
g tomorrow 5/30	
	Elsaid, Olivia < <u>oelsa</u>

Hi Francis,

See attached the latest version of the slides for the meeting tomorrow.

Thank you,
Nina
Nina Gonzalez Deloitte Consulting LLP Tel/Direct: +1 202 748 6535 ningonzalez@deloitte.com   www.deloitte.com Please consider the environment before printing.
From: Collins, Francis (NIH/OD) [E] b6  Sent: Friday, May 29, 2020 8:32 PM  To: Wholley, David (FNIH) [T] b6  Cc: Adam, Stacey (FNIH) [T] b6  Freire, Maria (FNIH) [T] b6  Subject: [EXT] RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30  Hoping these are coming to me soon, as I may want to do some editing — and then I wanted to run them past Janet tonight.
FC
From: Wholley, David (FNIH) [T]
makes the changes.  From: Collins, Francis (NIH/OD) [E] b6
Sent: Friday, May 29, 2020 5:59 PM  To: Wholley, David (FNIH) [T] b6  Cc: Adam, Stacey (FNIH) [T] b6   Freire, Maria (FNIH) [T] b6  ; Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] b6    Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30</ningonzalez@deloitte.com>
Hi all,
I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

We'll be on standby for any edits you may have.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note – has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis

From: Wholley, David (FNIH) [T]		b6				
Sent: Friday, May 29, 2020 1:59 Pl	M					
To: Collins, Francis (NIH/OD) [E]		b6				
Cc: Adam, Stacey (FNIH) [T]	b6	Freire, N	1aria (FNIH) <mark>[</mark>	[T]	b6	; Gonzalez, Nina
<ningonzalez@deloitte.com>; Par</ningonzalez@deloitte.com>	ker, Ashl	ley (NIH/OD) [E	E] [	b6	>	
Subject: Key messages re: immuno	omodula	tors for slides	for Moncef r	neeting to	morrow 5/3	30

## Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a portfolio approach to addressing the dramatic health and economic
  challenges posed by the pandemic, with harmonized efforts that address both disease etiology and
  symptomology.
  - o ACTIV Baricitinib (ACTT2, sponsored by NIAID) in progress
  - ACTIV hiVIG (sponsored by NIAID) in progress
  - ACTIV-1 Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) (Phase III) ready to launch late June
  - ACTIV-2*— Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
  - ACTIV-3* Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
  - ACTIV-4 Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually,
     Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS "Master" Network) (Phase II/III) –
     projected launch late June
  - ACTIV-5 De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) similar design to the mAb protocols, networks/sites/agents in discussions now projected launch August (if needed; i.e. if agents are not incorporated into mAb protocols)
     * current priority

[for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base

- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
   [Key Criteria for Scoring (slide 15 from 5/20) can go to backup
- Prioritization and Protocol Design: Who is Involved two-box slide containing names and affiliations of those involved in the Proritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
  - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)

- 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
- All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials
   = high POS
- Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
- Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
- o Protocol is 80% complete
  - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
    - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
  - All three companies have written their sections of the protocols, which are being merged into the master design
- Working with OWS/BARDA on choice of CRO to run the trial; revised cost estimate = \$60 million
- "ACTIV-4" Protocol for anticoagulants
  - Need bullets from NHBLI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS "network of networks" with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley Senior Vice-President, Research Partnerships <u>Foundation for</u> the National Institutes of Health

b6

mih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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v.E.1

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Subject:	Follow-up from	ACTIV TX-Clinical	Working Group Meeting	#8		
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	Coagulonathy	of Coronavirus Di	casca 2019 95637 ndf	2020-05-28	TV-Clinical MG Mosting St	immany ndf

# Dear ACTIV TX-Clinical WG,

Thank you for another good discussion at our meeting yesterday. We'd like to thank our NHLBI colleagues who presented on their anticoagulation trial plans. I also appreciate all the feedback provided to the Agent Prioritization – mAb Sub team and on the RFI Survey Tool, which I will distribute to this group when live.

Please find attached the formal summary from the meeting. In addition, please find a couple of papers that Tim was kind enough to share with the group around anticoagulation treatment on the front lines of COVID-19.

The first is a reasonable primer for people who are not treating COVID patients with anticoagulation therapies. The authors are from the expert panel that presented to BARDA about 3.5 weeks ago that some of this group attended. https://journals.lww.com/ccmjournal/Abstract/9000/Coagulopathy of Coronavirus Disease 2019.95637.aspx

Also another paper that endeavors to estimate the failure of 'routine' VTE prophylaxis for COVID treatment.

https://journals.lww.com/ccmjournal/Abstract/9000/Routine	Venous	Thromboembolism	Prophylaxis	May	Be.95638.
Thanks,					
Stacey					
Stacey J. Adam, PhD Director, Cancer Research Partnerships Direct: b6   Mobile: b6					

From:	Adam, Stacey (FN (FYDIBOHF23SPD							
Sent:	5/30/2020 2:39:3	3 AM						
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	b6	)	; Proschan,	Michael (NIH/N	IAID) [E] [/o=	ExchangeL	abs/ou=Exchan	ge
	Administrative Gr	oup (FYDIB	ÖHF23SPDLT)/cr	n=Recipients/cn	=7b45059209	b4468bb4	ba02b0dfbbb3	e4-proscham];
	Miller, Marissa A	(NIH/NHLB	I) [E] [/o=Exchan	geLabs/ou=Exch	ange Admini	strative Gr	oup	
	(FYDIBOHF23SPD	LT)/cn=Reci	ipients/cn=afea8	bcd1c054bcd92	50da63e1db	e947-mille	rma2]; Rachel H	larrigan
	b6		; William Erha	rdt b	6 );	Price, Dio	nne (FDA/CDEF	3)
	[/o=ExchangeLab	s/ou=Excha	nge Administrati	ve Group				
	(FYDIBOHF23SPD	LT)/cn=Reci	ipients/cn=a583e	eced842c44b18	bb6fcd3820b	ee21-price	d.fda]; Rubin, [	aniel B.
	(FDA/CDER) [/o=E	xchangeLa	bs/ou=Exchange	Administrative	Group			
	(FYDIBOHF23SPD	LT)/cn=Reci	ipients/cn=35c28	391059134111a	3ed28f92904	2aad-RUBI	ND.fda]; Farley	, John
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	(FYDIBOHF23SPD	LT)/cn=Reci	ipients/cn=40b4d	:4456b1446478	8f31fe7bcaa0	9bc-FARLI	EYJ.fda];	b6
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	(FYDIBOHF23SPD		-		c4cd4f75ef65	59f5-jroa.s	-3.co]; LHosey@	s-3.com; Kim,
	Peter (NIH/NIAID)					-		
	(FYDIBOHF23SPD						2]	
CC:	Demarcus	b6		as, Karen (FNIH			-	dministrative
	Group (FYDIBOHF	23SPDLT)/c		•			_	
	[jwachtel@deloit							•
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	b6					Smith,		
	b6		; Paul Klekotka	lr b6	i Ai	ay Nirula		; Chen,
	Helen Q. [qingche	n@deloitte	e.com]			<b>/</b>		
Subject:	Joint ACTIV 2 and	1 ACTIV 2 VA	Iriting Toom Man	ting				
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Show Time As: Tentative

Required	Jim Neaton; Jens Lundgren; Eric Hu	ughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina
Attendees:	(OS/ASPR/BARDA); Patterson, Amy	y (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI)
		Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Miller, Marissa
		; William Erhardt; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley,
	John (FDA/CDER);	hê .
	(NIH (NIAID) [E], Pag. Ibaanna,	b6 Javan, Arzhang b6 J; Kim, Peter (NIH/NIAID) [E]
Optional	(NIH/NIAID) [E]; Roa, Jhoanna;	b6 ; Kim, Peter (NIH/NIAID) [E] T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa;
Attendees:		ul Klekotka; Ajay Nirula; Chen, Helen Q.
~		
Stacey Ada	m is inviting you to a scheduled	d Zoom meeting.
Join Zoom	Meeting	
		b6
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Meeting ID	b6	
Password:	b6	
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<u></u>		US (Germantown)
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į	US (San Jose)	
Meeting ID	·	
Password:	b6	
i	ocal number:	h6

From: Mascola, John (NIH/VRC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F78B40A596B4CA4A2850A429D1AE3F2-JMASCOLA]

**Sent**: 5/14/2020 1:02:32 PM

To: Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Collins, Francis

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Lane, Cliff (NIH/NIAID) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane] Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Wholley, David (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]

Subject: RE: ChAdOx1

Flag: Follow up

Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3.

One issues is	b4,b5	
	b4,b5	

John

CC:

From: Marks, Peter b6

Sent: Thursday, May 14, 2020 6:23 AM

To: Collins, Francis (NIH/OD) [E] b6 Mascola, John (NIH/VRC) [E] b6; Lane, Cliff (NIH/NIAID) [E] b6

Cc: Fauci, Anthony (NIH/NIAID) [E] b6 Parker, Ashley (NIH/OD) [E] b6

Subject: RE: ChAdOx1

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

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On the manufacturing front		b4,b5		
		b4,b5		
Best Regards,				
Peter				
From: Collins, Francis (NIH/OD	) [E] [	b6		
Sent: Thursday, May 14, 2020	5:38 AM			
To: Mascola, John R (NIH)	b6	›; Lane, Henry C (NIH)	b6	; Marks, Peter
b6		<u> </u>		
Cc: Fauci, Anthony S (NIH)	b6	; Wholley, David N (NIH)	b6	; Tabak, Lawrence A
(NIH) d6	; Parker, As	shley S (NIH) <b>b6</b>		
Subject: ChAdOx1		<u> </u>		

## Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Thanks, Francis

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1C655040D47346C7B04D7BC11A403ECB-WOLINETZCD] Sent: 5/14/2020 1:19:09 PM To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl] Subject: FW: ChAdOx1 Just jumping in briefly to say that Ashley has mentioned some disguiet to me - prior to this email - that the industry chair of this WG seemed conflicted. She said it felt like ( b4,b5 ba,b5, but since the NIH folks on the group didn't push back she wasn't sure if she was misreading things. She doesn't know the players involved and neither do I, so take that observation for whatever it's worth. But thought it was more interesting in light of this email from John. From: Mascola, John (NIH/VRC) [E] Sent: Thursday, May 14, 2020 9:03 AM b6 Collins, Francis (NIH/OD) [E] To: Marks, Peter (FDA/CBER) Cliff (NIH/NIAID) [E]! b6 ; Wholley, David (FNIH) [T] Cc: Fauci, Anthony (NIH/NIAID) [E] Tabak, Lawrence (NIH/OD) [E] ; Parker, Ashley (NIH/OD) [E] Subject: RE: ChAdOx1 Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3. One issues is t **b4,b5** John From: Marks, Peter 4 **Sent:** Thursday, May 14, 2020 6:23 AM To: Collins, Francis (NIH/OD) [E] ; Mascola, John (NIH/VRC) [E] Cliff (NIH/NIAID) [E] ; Wholley, David (FNIH) [T] Cc: Fauci, Anthony (NIH/NIAID) [E] ; Parker, Ashley (NIH/OD) [E] Lawrence (NIH/OD) [E] Subject: RE: ChAdOx1 Dear Francis, We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my

last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially

as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Wolinetz, Carrie (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

From:

Among other things, Tony, John and I discussed the concept that in addition to harmonized protocols we would consider merging the first two vaccines that are currently aiming to start phase 3 into one master protocol if they appeared to be staying on schedule for a July 1 start. Planning on one DSMB for at least these two candidates therefore makes a lot of sense.

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On the manufacturing front		b4,b5	5	
		b4,b5		
Best Regards,				
Peter				
From: Collins, Francis (NIH/OD)	[E] [	b6		
<b>Sent:</b> Thursday, May 14, 2020 5	·			
To: Mascola, John R (NIH)	b6	Lane, Henry C (NIH	) <b>b6</b>	; Marks, Peter
b6				
Cc: Fauci, Anthony S (NIH)	b6	; Wholley, David N (N	H) <b>€ b6</b>	; Tabak, Lawrence A
(NIH) <b>b6</b>	; Parker, A	Ashley S (NIH) <b>b6</b>	•	
Subject: ChAdOx1	-	<b>'</b>	<del></del>	

# Gentlemen:

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Thanks, Francis

From:	Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP			
<u> </u>	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]			
Sent:	5/14/2020 2:45:11 PM  Marks, Peter b6 ; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange			
То:	Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group			
CC:	(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane] Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group			
cc.	(FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group			
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]			
Subject:	RE: ChAdOx1			
Yes, I'd be gl	lad to join. We should start with Dolsten.			
From: Marks,	Peter b6			
Sent: Thursda	ay, May 14, 2020 9:05 AM			
To: Mascola	John (NIH/VRC) [F] b6 b: Collins Francis (NIH/OD) [F] b6 Jane			
Cliff (NIH/NIA	Description   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color   Color			
Cc: Fauci, Ant	hony (NIH/NIAID) [E] <b>b6</b> Wholley, David (FNIH) [T] <b>b6</b> Tabak,			
Lawrence (NII	H/OD) [F] b6 Parker, Ashley (NIH/OD) [F] b6			
Subject: RE: C				
Judject. RE. C	SIAUOAI			
Dear John,				
Thanks for bringing the Pfizer issue up. I think that a call with their head of development and possibly also their CEO may be needed, and I wonder if Francis would like to join?				
D L D l -				
Best Regards,				
Peter				
From: Mascol	la, John (NIH/VRC) [E] <b>b6</b>			
Sent: Thursda	ay, May 14, 2020 9:03 AM			
To: Marks, Pe	ter b6 ; Collins, Francis S (NIH) b6 ; Lane, Henry C (NIH)			
b6				
Cc: Fauci. Ant	thony S (NIH) b6 Wholley, David N (NIH) def b6 ; Tabak, Lawrence A b6 Parker, Ashley S (NIH) b6			
(NIH)	b6 Parker Ashley S (NIH) b6			
Subject: RE: C	ThAdOx1			
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Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we				
presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and				
general agree	ement, with some useful recommendations on efficient ways to conduct phase 3.			
	b4,b5			
One issues !	VU,FU 			
	b4,b5			
	NT.NJ			
	J			

From: Marks, Peter	b6				
Sent: Thursday, May 14,	, 2020 6:23 AM	·			
To: Collins, Francis (NIH,	/OD) [E]	b6	Mascola, John (NIH/VRC) [E]	b6	; Lane,
Cliff (NIH/NIAID) [E]	b6				
Cc: Fauci, Anthony (NIH)	/NIAID) [E]	b6	Wholley, David (FNIH) [T]	b6	Tabak,
Lawrence (NIH/OD) [E]	b6		Parker, Ashley (NIH/OD) [E]	b6	
Subject: RE: ChAdOx1			L		!

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Best Regards,				
Peter				
From: Collins, Francis (NIH/	OD) [E]	<b>06</b>		
Sent: Thursday, May 14, 20	20 5:38 AM			
To: Mascola, John R (NIH)	b6	; Lane, Henry C (NIH)	b6	, Marks, Peter
b6		··		
Cc: Fauci, Anthony S (NIH)	b6	Wholley, David N (NIH)	b6	Tabak, Lawrence A
(NIH) b6	Parker, Ash	ley S (NIH) <b>b6</b>		
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From: Mascola, John (NIH/VRC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F78B40A596B4CA4A2850A429D1AE3F2-JMASCOLA] Sent: 5/14/2020 2:52:17 PM To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane] CC: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd] RE: ChAdOx1 Subject: I don't sense that other companies have any major concerns. Merck, JJ, Sanofi – all part of good productive discussion. But Pfizer's two representatives spoke more than all the other companies combined for this particular hour call. I'd ask Dough to give his perspective here. b6 From: Collins, Francis (NIH/OD) [E] Sent: Thursday, May 14, 2020 10:32 AM b6 ; Marks, Peter (FDA/CBER) To: Mascola, John (NIH/VRC) [E] Lane, Cliff (NIH/NIAID) [E] b6 ; Wholley, David (FNIH) [T] Cc: Fauci, Anthony (NIH/NIAID) [E] ; Tabak, Lawrence (NIH/OD) [E] ; Parker, Ashley (NIH/OD) [E] b₆ Lowy, Douglas (NIH/NCI) [E] Subject: RE: ChAdOx1 Thanks for this input, John and Peter. It's too bad that Pfizer is dominating the discussion about the DSMB, when they apparently don't intend to take part in the harmonized master protocol anyway. Are there other companies represented on the Vaccines WG who might feel differently? I'm looping in Doug (and should have done so earlier, sorry!). Francis From: Mascola, John (NIH/VRC) [E] b6 Sent: Thursday, May 14, 2020 9:03 AM b6 To: Marks, Peter (FDA/CBER) Collins, Francis (NIH/OD) [E] ; Lane, Cliff (NIH/NIAID) [E] b6 Wholley, David (FNIH) [T] Cc: Fauci, Anthony (NIH/NIAID) [E] ; Tabak, Lawrence (NIH/OD) [E] { b6 Parker, Ashley (NIH/OD) [E]

Subject: RE: ChAdOx1

APAR0000006218

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One issues i	b4,b5
1_ 4	<b>b5</b>

John

From: Marks, Peter	b6	}			
Sent: Thursday, May 1	4, 2020 6:23 AM	·			
To: Collins, Francis (NI	H/OD) [E] [	b6	Mascola, John (NIH/VRC) [E]	b6	; Lane,
Cliff (NIH/NIAID) [E]	b6				
Cc: Fauci, Anthony (NI	H/NIAID) [E] [	b6	Wholley, David (FNIH) [T]	b6	; Tabak,
Lawrence (NIH/OD) [E	b6		Parker, Ashley (NIH/OD) [E]	b6	
Subject: RE: ChAdOx1			\ <u></u>		

Dear Francis,

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On the manufacturing front f		]				
b4,b5						

Best Regards, Peter

From: Collins, Francis (NIH/OD	) [E] [	o6		
Sent: Thursday, May 14, 2020	5:38 AM			
To: Mascola, John R (NIH)	b6	Lane, Henry C (NIF	l) <b>b6</b>	; Marks, Peter
b6		<del></del>		
Cc: Fauci, Anthony S (NIH)	b6	Wholley, David N (N	IH) <b>b</b> 6	; Tabak, Lawrence A
(NIH) b6	; Parker, Ash	nley S (NIH) <b>b6</b>		
Subject: ChAdOx1		i	i	

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

From: Lowy, Douglas (NIH/NCI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F1B7B8FE4739478BB17840C56902718A-LOWYD] Sent: 5/14/2020 3:06:20 PM To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane] CC: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras] Re: ChAdOx1 Subject: Francis: I don't know the perspective of the other companies. As Kathrin realizes, the regulatory perspective will be important. Doug From: "Collins, Francis (NIH/OD) [E]" Date: Thursday, May 14, 2020 at 10:32 AM To: "Mascola, John (NIH/VRC) [E]" b6 , "Marks, Peter (FDA/CBER)" "Lane, Cliff (NIH/NIAID) [E]" "Wholley, David (FNIH) [T]" Cc: "Fauci, Anthony (NIH/NIAID) [E]"["" b6 , "Tabak, Lawrence (NIH/OD) [E]" "Parker, Ashley (NIH/OD) "Lowy, Douglas (NIH/NCI) [E]" [E]" Subject: RE: ChAdOx1 Thanks for this input, John and Peter. It's too bad that Pfizer is dominating the discussion about the DSMB, when they apparently don't intend to take part in the harmonized master protocol anyway. Are there other companies represented on the Vaccines WG who might feel differently? I'm looping in Doug (and should have done so earlier, sorry!). Francis From: Mascola, John (NIH/VRC) [E] b6 Sent: Thursday, May 14, 2020 9:03 AM Collins, Francis (NIH/OD) [E] To: Marks, Peter (FDA/CBER) Lane, Cliff (NIH/NIAID) [E] Cc: Fauci, Anthony (NIH/NIAID) [E] b₆ ; Wholley, David (FNIH) [T] Tabak, Parker, Ashley (NIH/OD) [E] Lawrence (NIH/OD) [E] b6 Subject: RE: ChAdOx1

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One issues i	b4,b5
	<b>b5</b>

John

From: Marks, Peter	b6				
Sent: Thursday, May 14, 202	0 6:23 AM				
To: Collins, Francis (NIH/OD)	[E]	b6	Mascola, John (NIH/VRC) [E]	b6	; Lane
Cliff (NIH/NIAID) [E]	b6	<u> </u>			
Cc: Fauci, Anthony (NIH/NIAI	D) [E]	b6	Wholley, David (FNIH) [T]	b6	Tabak,
Lawrence (NIH/OD) [E]	b6		Parker, Ashley (NIH/OD) [E]	b6	
Subject: RE: ChAdOx1					

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On the manufacturing front	b4,b5	
	b4,b5	

Best Regards, Peter

From: Collins, Francis (NIH/OD	) [E]	b6			
Sent: Thursday, May 14, 2020	5:38 AM				
To: Mascola, John R (NIH) €	b6	; Lane,	Henry C (NIH) ₹	b6	; Marks, Peter
b6					
Cc: Fauci, Anthony S (NIH)	b6	Wholley	, David N (NIH) [	b6	Tabak, Lawrence A
(NIH) <u>b6</u>	Parker, A	Ashley S (NIH)	b6		
Subject: ChAdOx1		·			

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From: Sent: To: Subject:	Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD] 5/14/2020 5:23:45 PM Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf] RE: ChAdOx1
Flag:	Follow up
We can talk a	oout in the wr
Sent: Thursda To: Wholley, I Subject: RE: C	Francis (NIH/OD) [E] b6  y, May 14, 2020 1:23 PM  David (FNIH) [T] b6  hAdOx1  out, can we discuss at the 2:30 War Room? Or needs a private call?
Sent: Thursda To: Collins, Fr Subject: FW: 0	y, David (FNIH) [T] b6 y, May 14, 2020 12:05 PM ancis (NIH/OD) [E]  b6 ChAdOx1 minute to chat about this directly, Francis?
Sent: Thursda To: Mascola, J Cliff (NIH/NIA Cc: Fauci, Ant Lawrence (NII Subject: RE: C Dear John, Thanks for bri	hony (NIH/NIAID) [E] b6 ; Wholley, David (FNIH) [T] b6 ; Tabak, H/OD) [E] b6 ; Parker, Ashley (NIH/OD) [E] b6
<b>Sent:</b> Thursda <b>To:</b> Marks, Pe	hony S (NIH) { b6   Wholley, David N (NIH) { b6 } Tabak, Lawrence A b6   Parker, Ashley S (NIH)   b6

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b4,	<b>b5</b>

John

From: Marks, Peter	b6				
Sent: Thursday, May	14, 2020 6:23 AV				
To: Collins, Francis (N	NIH/OD) [E] {	b6	; Mascola, John (NIH/VRC) [E]	b6	Lane,
Cliff (NIH/NIAID) [E]	b6				
Cc: Fauci, Anthony (N	NIH/NIAID) [E]	b6	; Wholley, David (FNIH) [T]	b6	; Tabak,
Lawrence (NIH/OD) [	E] b6		; Parker, Ashley (NIH/OD) [E]	b6	
Subject: RE: ChAdOx	1		<u> </u>		/

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On the manufacturing front	b4,b5	
	b4,b5	

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From: Collins, Francis (NIH/OD)	[E]	b6		
Sent: Thursday, May 14, 2020 5	:38 AM			
To: Mascola, John R (NIH) 4	b6	⟩; Lane, Henry C (NIH)	b6	; Marks, Peter
b6				
Cc: Fauci, Anthony S (NIH)	b6	; Wholley, David N (NIH) <	b6	; Tabak, Lawrence A
(NIH) [	; Parker, A	Ashley S (NIH) <b>b6</b>	}	
Subject: ChAdOx1		<u> </u>	/	

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From:	Marks, Peter <b>b6</b>
Sent:	5/17/2020 12:04:58 AM
To:	Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Fauci, Anthony (NIH/NIAID)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Mascola, John (NIH/VRC) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Lane, Cliff (NIH/NIAID) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC:	Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
~~·	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD)
	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E]
	[/o=ExchangeLabs/ou=Exchange Administrative Group
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject:	RE: ChAdOx1
D F	
Dear Francis,	
!	
	h1 h5
	b4,b5
b4,b5	
Best Regards,	
Peter	
reter	
	5 · (NW) (ON) [5]   <b>h6</b>
	Francis (NIH/OD) [E] <b>b6</b>
Sent: Saturda	y, May 16, 2020 8:00 PM
Sent: Saturda To: Marks, Pe	y, May 16, 2020 8:00 PM  ter b6 ; Fauci, Anthony S (NIH) b6 ; Mascola, John R (NIH)
Sent: Saturda To: Marks, Pe	y, May 16, 2020 8:00 PM  ter b6 ; Fauci, Anthony S (NIH) b6 ; Mascola, John R (NIH)  Lane, Henry C (NIH) b6
Sent: Saturda To: Marks, Pe bo Cc: Wholley, [	y, May 16, 2020 8:00 PM  ter b6 ; Fauci, Anthony S (NIH) b6 ; Mascola, John R (NIH)  Lane, Henry C (NIH) b6  David N (NIH) b6 ; Tabak, Lawrence A (NIH) b6 ; Parker, Ashley S
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Sent: Saturda To: Marks, Pe bo Cc: Wholley, I (NIH) { Subject: RE: C	y, May 16, 2020 8:00 PM  ter   b6
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Sent: Saturda To: Marks, Pe bo Cc: Wholley, I (NIH) { Subject: RE: C	y, May 16, 2020 8:00 PM  ter   b6
Sent: Saturda To: Marks, Pe bi Cc: Wholley, [ (NIH) { Subject: RE: C Just a brief w	y, May 16, 2020 8:00 PM  ter
Sent: Saturda To: Marks, Pe bl Cc: Wholley, I (NIH) { Subject: RE: C  Just a brief w  From: Marks,	y, May 16, 2020 8:00 PM  ter   b6
Sent: Saturda To: Marks, Pe bl Cc: Wholley, I (NIH) { Subject: RE: C  Just a brief w  From: Marks,	y, May 16, 2020 8:00 PM  ter
Sent: Saturda To: Marks, Pe bi Cc: Wholley, I (NIH) { Subject: RE: C  Just a brief w  From: Marks, Sent: Saturda To: Fauci, Ant	y, May 16, 2020 8:00 PM  ter   b6
Sent: Saturda To: Marks, Pe bu Cc: Wholley, I (NIH) ₹ Subject: RE: C  Just a brief w  From: Marks, Sent: Saturda To: Fauci, Ant Collins, Franci	y, May 16, 2020 8:00 PM    tter
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Sent: Saturda To: Marks, Pe bi Cc: Wholley, I (NIH) { Subject: RE: C  Just a brief w  From: Marks, Sent: Saturda To: Fauci, Ant Collins, Franci Cc: Wholley, I Ashley (NIH/C	y, May 16, 2020 8:00 PM  ter

Will certainly include you next week on this call.

Best Regards, Peter From: Fauci, Anthony (NIH/NIAID) [E] **Sent:** Thursday, May 14, 2020 9:12 AM 

 To: Marks, Peter 
 b6
 ⇒; Mascola, John R (NIH) 
 b6

 b6
 Lane, Henry C (NIH) 
 b6

 ; Collins, Francis S (NIH) Cc: Wholley, David N (NIH) ; Parker, Ashley S Subject: RE: ChAdOx1 I would also like to be on that call with the Pfizer CEO if we could possible arrange it. Anthony S. Fauci, MD Director National Institute of Allergy and Infectious Diseases Building 31, Room 7A-03 31 Center Drive, MSC 2520 National Institutes of Health Bethesda, MD 20892-2520 Phone: **b6** FAX: (301) 496-4409 E-mail: The information in this e-mail and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of the NIAID by one of its representatives. From: Marks, Peter de b6 **Sent:** Thursday, May 14, 2020 9:05 AM ; Collins, Francis (NIH/OD) [E] { b6 } Lane, To: Mascola, John (NIH/VRC) [E] Cliff (NIH/NIAID) [E] b6 Subject: RE: ChAdOx1 Dear John, Thanks for bringing the Pfizer issue up. I think that a call with their head of development and possibly also their CEO may be needed, and I wonder if Francis would like to join? Best Regards, Peter From: Mascola, John (NIH/VRC) [E] Sent: Thursday, May 14, 2020 9:03 AM b6 Lane, Henry C (NIH) ; Collins, Francis S (NIH) To: Marks, Peter b6 ; Wholley, David N (NIH) b6 Tabak, Lawrence A Cc: Fauci, Anthony S (NIH)

(NIH)	b6	Parker, Ashley S (NII	H) [	b6		
Subjec	t: RE: ChAdOx1					
presen	ted the harmonized pro	ogress on ACTIV Vaccine tocol approach and high useful recommendatior	n level details	of phase 3 design. T	There was good in	
One iss	ues i		b4,b5			þ
		b	4,b	5		
John						
Sent: T	Marks, Peter hursday, May 14, 2020 lins, Francis (NIH/OD) [E		; Mascola, Joh	ın (NIH/VRC) [E]	b6	Lane,
Cc: Fau Lawrer	IH/NIAID) [E] ci, Anthony (NIH/NIAID ce (NIH/OD) [E] t: RE: ChAdOx1	b6	; Wholley, rker, Ashley (N	David (FNIH) [T] NIH/OD) [E]	b6 b6	; Tabak,
Dear Fi	ancis,					
last cor	nversation with the AZ o	rith the Oxford AZ team linical team they were o the timing was right. Th	on board with	the USG concept o	f a large phase 3 ti	-
mergin	g the first two vaccines	n and I discussed the co that are currently aimin start. Planning on one	g to start phas	se 3 into one maste	er protocol if they	appeared to be
though	it certainly involves sign	vith John again about thi nificant extra work in pro o contingencies simultar	otocol develo			
1)		Z enter phase 3 at differ cols, non-overlapping si			part), in which cas	e we will go
2)	on one master protoco worth the effort in plan	NZ enter phase 3 simulta of making use of all availa nning even if circumstan of by 10,000; 2) could hel ative efficacy data.	able sites. The nces preclude	ere is much to reco proceeding along t	mmend this optio his path: 1) it could	n, such that it is d reduce the
On the	manufacturing front		b	4,b5		
		_	4.b5			; ;

Best Regards, Peter

From: Collins, Francis (NIH/OD	) [E] [	b6				
Sent: Thursday, May 14, 2020	5:38 AM		<i>ı</i> -			
To: Mascola, John R (NIH)	b6	; Lane, F	lenry C (NIH)	l	b <b>6</b>	; Marks, Peter
b6						
Cc: Fauci, Anthony S (NIH)	b6	; Wholley,	, David N (NIH)	-	b6	; Tabak, Lawrence A
(NIH) <b>b6</b>	; Parker,	Ashley S (NIH)	b6	>		
Subject: ChAdOx1		·				

## Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Sent: 5/17/2020 7:09:19 PM To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd] Subject: RE: ChAdOx1 I'm speaking to Dolsten at 6:30 PM this evening – following up an email that seemed to suggest he wanted to talk. I'll let everybody know what happens then. From: Wholley, David (FNIH) [T] Sent: Sunday, May 17, 2020 2:16 PM To: Collins, Francis (NIH/OD) [E] Subject: RE: ChAdOx1 Thanks – sorry, sent my other note before I saw this one. From: Collins, Francis (NIH/OD) [E] Sent: Saturday, May 16, 2020 8:00 PM To: Marks, Peter (FDA/CBER) Fauci, Anthony (NIH/NIAID) [E] b6 ; Lane, Cliff (NIH/NIAID) [E] Mascola, John (NIH/VRC) [E] Cc: Wholley, David (FNIH) [T] ; Parker, ; Tabak, Lawrence (NIH/OD) [E] Ashley (NIH/OD) [E] [ b₆ Subject: RE: ChAdOx1 **b4,b5** Just a brief word of concern **b4,b5** From: Marks, Peter **Sent:** Saturday, May 16, 2020 3:13 PM ; Mascola, John (NIH/VRC) [E] To: Fauci, Anthony (NIH/NIAID) [E] ] Lane, Cliff (NIH/NIAID) [E] Collins, Francis (NIH/OD) [E] j; Tabak, Lawrence (NIH/OD) [E] Cc: Wholley, David (FNIH) [T] Parker, Ashley (NIH/OD) [E] b6 Subject: RE: ChAdOx1 Dear Tony, Will certainly include you next week on this call. Best Regards, Peter From: Fauci, Anthony (NIH/NIAID) [E] Sent: Thursday, May 14, 2020 9:12 AM To: Marks, Peter b6 ; Mascola, John R (NIH) ; Collins, Francis S (NIH) Lane, Henry C (NIH) < b6 ; Parker, Ashley S Cc: Wholley, David N (NIH) b6 Tabak, Lawrence A (NIH)

Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]

From:

would also like to be on that call with the Pfizer CEO if we could possible arrange it.
Anthony S. Fauci, MD  Director  National Institute of Allergy and Infectious Diseases  Building 31, Room 7A-03  31 Center Drive, MSC 2520  National Institutes of Health  Bethesda, MD 20892-2520  Phone:
The information in this e-mail and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not accept liability for any statements made that are the sender's pown and not expressly made on behalf of the NIAID by one of its representatives.
From: Marks, Peter { b6   Sent: Thursday, May 14, 2020 9:05 AM   Fo: Mascola, John (NIH/VRC) [E]   b6   ; Collins, Francis (NIH/OD) [E]   b6   ; Lane, Cliff (NIH/NIAID) [E]   b6   ; Collins, Francis (NIH/OD) [E]   b6   ; Lane, Cliff (NIH/NIAID) [E]   b6   ; Tabak, Lawrence (NIH/OD) [E]   b6   Parker, Ashley (NIH/OD) [E]   b6   Subject: RE: ChAdOx1
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Best Regards, Peter
From: Mascola, John (NIH/VRC) [E] b6  Sent: Thursday, May 14, 2020 9:03 AM  Fo: Marks, Peter b6; Collins, Francis S (NIH) b6; Lane, Henry C (NIH)  b6  Cc: Fauci, Anthony S (NIH) b6; Wholley, David N (NIH) b6  NIH) b6; Parker, Ashley S (NIH) b6  Subject: RE: ChAdOx1
Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3.
One issues b4,b5
b4,b5

(NIH) **b6**Subject: RE: ChAdOx1

# b4,b5

John

From: Marks, Peter	b6				
Sent: Thursday, May 14, 2	2020 6:23 AM				
To: Collins, Francis (NIH/C	DD) [E]	b6	; Mascola, John (NIH/VRC) [E]	b6	; Lane,
Cliff (NIH/NIAID) [E]	b6				
Cc: Fauci, Anthony (NIH/N	NAID) [E]	b6	>; Wholley, David (FNIH) [T]	b6	ː}; Tabak,
Lawrence (NIH/OD) [E] {	b6		Parker, Ashley (NIH/OD) [E]	b6	}
Subject: RE: ChAdOx1					

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Among other things, Tony, John and I discussed the concept that in addition to harmonized protocols we would consider merging the first two vaccines that are currently aiming to start phase 3 into one master protocol if they appeared to be staying on schedule for a July 1 start. Planning on one DSMB for at least these two candidates therefore makes a lot of sense.

Later today I will be speaking with John again about this merged concept. After giving it very careful consideration, though it certainly involves significant extra work in protocol development and logistic planning, I believe that we should be actively planning for the two contingencies simultaneously:

- 1) Moderna and Oxford AZ enter phase 3 at different times (more than 2 weeks apart), in which case we will go with harmonized protocols, non-overlapping sites, and a single DSMB, and
- 2) Moderna and Oxford AZ enter phase 3 simultaneously (less than 2 weeks apart), in which case we should plan on one master protocol making use of all available sites. There is much to recommend this option, such that it is worth the effort in planning even if circumstances preclude proceeding along this path: 1) it could reduce the overall size of the trials by 10,000; 2) could help drive enrollment since fewer people will receive placebo; and 3) it will produce comparative efficacy data.

On the manufacturing (		b4,b5		
		b4,b5		
Best Regards, Peter				
From: Collins, Francis (NIH/OD) [E]	b6			
<b>Sent:</b> Thursday, May 14, 2020 5:38 AM				
To: Mascola, John R (NIH) b	6	; Lane, Henry C (NIH)	b6	; Marks, Peter
b6 >		L		
Cc: Fauci, Anthony S (NIH) b	6	; Wholley, David N (NIH)	b6	; Tabak, Lawrence A

(NIH)	₽6	; Parker	, Ashley S (NIH)	b6	- }
Subje	ct: ChAdOx1			L	/

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And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Subject.	[/o=ExchangeLabs/ou=Excha (FYDIBOHF23SPDLT)/cn=Reci [/o=ExchangeLabs/ou=Excha (FYDIBOHF23SPDLT)/cn=Reci (NIH/OD) [E] [/o=ExchangeLa (FYDIBOHF23SPDLT)/cn=Reci [/o=ExchangeLabs/ou=Excha (FYDIBOHF23SPDLT)/cn=Reci	ipients/cn=2d7e36 nge Administrativo ipients/cn=73143c abs/ou=Exchange A ipients/cn=306b22 nge Administrativo ipients/cn=8598d5	8a3137473bbce161547 e Group l1860bc42458be254ca2 Administrative Group l44466140faa95aaaafe0 e Group	1573b23-anderson 06ebd70-parkeras];	njm]; Parker, Ashley	[E]
Subject:	RE: Woodcock summary of co	urrent triais				
Yes						
Sent: Tuesday To: Collins, Fra Austin, Christo Anderson, Jan Freire, Maria ( Subject: RE: W	y, David (FNIH) [T] r, May 12, 2020 10:08 PM ancis (NIH/OD) [E] opher (NIH/NCATS) [E] nes (NIH/OD) [E] (FNIH) [T] voodcock summary of curre	b6 b6 ent trials	abak, Lawrence (NIH/ }, Lane, Cliff (NIH/I }; Parker, Ashley (N	VIAID) [E	<b>b6</b>	
From: Collins,	Francis (NIH/OD) [E] {	b6				
	, May 12, 2020 9:43 Plvi		İ	<b>,</b>		
	vrence (NIH/OD) [E]	b6	Wholley, David	,	<b>b6</b> >; Austin,	
	4111/14CA13/[L] L		ne, Cliff (NIH/NIAID) [	(	; Anderson,	
James (NIH/OI (FNIH) [T] <b>Subject:</b> Wood	D) [E] { b6 b6 dcock summary of current		, Ashley (NIH/OD) [E]	b6	; Freire, Maria	
Interesting in	nventory from Janet					
From: Woodco	ock lanet b	6				
Sant: Tuesday	May 12 2020 0:28 PM		i			
<b>To:</b> Collins, Fra	ancis (NIH/OD) [E]	b6				
<b>Subject:</b> RE: Le	etter to the ACTIV Executiv	e Committee fro	m the Therapeutics-C	Clinical Working G	roup	
-	nare. It's a bit out of date. A Id have soon. Need to fill in			-	_	
From: Collins,	Francis (NIH/OD) [E]	b6				

Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD)

(FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E]

(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher

From:

Sent:

To:

5/13/2020 9:22:41 AM

Sent: Tuesday, May 12, 2020 10:46 AM  To: Collins, Francis S (NIH) b6 Stoffels, Paul [JJCUS] ← b6 ; Fauci, Anthony S (NIH)
From: Wholley, David (FNIH) [T] b6
Can we discuss before tomorrow? jw
Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group
To: Collins, Francis (NIH/OD) [E] b6
From: Woodcock, Janet { b6 Sent: Tuesday, May 12, 2020 11:28 AM
Yes, I would like that. Can you do 3:30?
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group
To: Woodcock, Janet b6
Date: May 12, 2020 at 12:49:32 PM EDT
From: Collins, Francis (NIH/OD) [E] b6
No have to brief higher ups. Later better. Jwv
oubject. Re. Letter to the ACTIV executive Committee from the Therapeutics-Clinical Working Group
To: Collins, Francis (NIH/OD) [E]   b6  Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group
Sent: Tuesday, May 12, 2020 1:08 PM
From: Woodcock, Janet <b>b6</b>
5 pm? <b>b6</b> if you can. Otherwise after 7 pm is good
<b>To:</b> Woodcock, Janet <b>b6 Subject:</b> RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group
Sent: Tuesday, May 12, 2020 1:31 PM  To: Woodcock, Janet b6
From: Collins, Francis (NIH/OD) [E] 6
Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group
From: Woodcock, Janet { b6  Sent: Tuesday, May 12, 2020 5:01 PM  To: Collins, Francis (NIH/OD) [E] b6
From: Woodcock, Janet <b>b6</b>
Francis
share with ACTIV leadership?
just got to this e-mail (it's been that kind of day). Wow, there is a LOT of useful information here. May I
Hi Janet,
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group
To: Woodcock, Janet b6

b6	Gibbons	, Gary H (NIH)		6	Woodcock, Janet		
<b>b6</b>		Pao, William		,	; Dolsten, Mikael		
Cc: Colvis, Christine N	/ (NIH) {	<u>b</u> 6	; De	srosiers, Bets	y <b6< td=""><td></td><td>Hughes,</td></b6<>		Hughes,
Eric <b>b</b> 6		Read, Sarah	, , ,	b6	Jansen, Kathı		
b6		ırilla, Michael			>; Lowy, Doug	las R (NIH)	····!
b6	; Young, Jo		b6		e, Maria C (NIH)	Lor Achloy C/	j Tabak,
Lawrence A (NIH)		son, James M	Lane, Henry	b6		ker, Ashley S ( istopher P (NI	
<b>b6</b>	1 '	tz, Carrie D (N		b6		istopher i (ivii	117
Subject: FW: Letter to		•	, ,_,_,_,		 utics-Clinical Working	Group	
•				·	J	•	
Dear ACTIV Executive							
			•		king Group received th		
		_			nce. While we expect		
				-	is to hear from all of t ay be facing challenge	-	-
discuss strategy movi		•	vorking and v	where they m	ay be racing challenge	es in ACTIV, an	a jointly
discuss strategy movi	ng ioi wara.						
David							
From: Adam, Stacey	[FNIH] [T]	b6	<del></del>				
Sent: Tuesday, May 1	· · · · · · · · · · · · · · · · · · ·	2 AM	=.=!				
<b>To:</b> Wholley, David (F	NIH) [T] <u>{</u>	b6		,			
Cc: Read, Sarah (NIH)		b6	}; Er	ic Hughes 🚛	b6	lCarlos O	Garner
b6	j; Ju	dy Currier	b6		; Keith Gottesdiener	/	(
b6		iAmanda Per		b		ein, Peter (FDA	(/CDER)
Subject: Letter to the		s, Elizabeth (N			<b>6</b> ் ந் <u>eikim@c</u> -Clinical Working Gro	leloitte.com	
Subject: Letter to the	ACTIV EXEC	utive Commit	tee from the	merapeutics	-Clinical Working Gro	up	
Hi David,							
,							
Please find attached	a letter from	n the Therape	utics-Clinical	Working Gro	up to the ACTIV Execu	tive Committe	e for their
	-				ges and issues that the	•	
group thinks the ACT	IV PPP is fac	ing, as well as	some very s	pecific reques	sts for assistance from	the ACTIV EC	for our
team.							
Please relay this to th	e ACTIV FC	for their revie	w Our grou	n would welc	ome any feedback the	v have	
, rease relay tims to ti	ic / (City LC	ioi dieli revie	our grou	p would well	ome any recubuck the	7 11440.	
Thanks,							
Stacey							
Stacey J. Adam, Phl	)						
Director, Cancer	~						

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

Foundation for the National Institutes of Health
Direct: b6 | Mobile: b6

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras] Subject: FW: Woodcock summary of current trials Attachments: jwnationalCOVID19therapeutics.pptx You asked me earlier about the list of 21 mAb companies Janet was referring to. See slide 8 from this deck FC distributed Tuesday, think that is it. From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, May 12, 2020 9:43 PM ; Wholley, David (FNIH) [T] To: Tabak, Lawrence (NIH/OD) [E] ; Austin, ; Lane, Cliff (NIH/NIAID) [E] Christopher (NIH/NCATS) [E] Anderson, b6 James (NIH/OD) [E] Parker, Ashley (NIH/OD) [E] ; Freire, Maria (FNIH) [T] Subject: Woodcock summary of current trials Interesting inventory from Janet... From: Woodcock, Janet Sent: Tuesday, May 12, 2020 9:38 PM To: Collins, Francis (NIH/OD) [E] b6 Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group Yes you can share. It's a bit out of date. As I said I'm doing a deeper dive on convalescent plasma and the neutralizing MoAbs. Should have soon. Need to fill in detail of all planned DOD and NIH studies. Should get to that this week. Jw From: Collins, Francis (NIH/OD) [E] Date: May 12, 2020 at 8:48:22 PM EDT To: Woodcock, Janet Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group Hi Janet, I just got to this e-mail (it's been that kind of day). Wow, there is a LOT of useful information here. May I share with ACTIV leadership? Francis From: Woodcock, Janet Sent: Tuesday, May 12, 2020 5:01 PM To: Collins, Francis (NIH/OD) [E] b6 Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]

From:

Sent:

To:

5/15/2020 1:24:33 AM

From: Collins, Francis (NIH/OD) [E] <b>b6</b>	
<b>Sent:</b> Tuesday, May 12, 2020 1:31 PM	
To: Woodcock, Janet b6	
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group	
Fund the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of	
5 pm? <b>b6</b> if you can. Otherwise after 7 pm is good	
From Woodcook longs b6	
From: Woodcock, Janet b6 Sont: Tuesday, May 13, 2020 1:08 PM	
Sent: Tuesday, May 12, 2020 1:08 PM  To: Collins, Francis (NIH/OD) [E] b6	
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group	
Subject. RE. Letter to the ACTIV Executive Committee from the Merapeutics-Chilical Working Group	
No have to brief higher ups. Later better. Jwv	
From: Collins, Francis (NIH/OD) [E] b6  Date: May 12, 2020 at 12:49:32 PM EDT	
To: Woodcock, Jane b6 Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group	
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From: Woodcock, Janet b6 Sent: Tuesday, May 12, 2020 11:28 AM	
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<b>Sent:</b> Tuesday, May 12, 2020 10:46 AM	
To: Collins, Francis S (NIH) b6 ; Stoffels, Paul [JJCUS] b6 Fauci, Anthony S (N	IIH)
be Gibbons Gary H (NIH)	,
b6 ; Pao, William b6 ; Dolsten, Mikael	
b6	
Cc: Colvis, Christine M (NIH) b6 ; Desrosiers, Betsy b6 ; Hu	ghes,
Eric <b>b6</b> Read, Sarah W (NIH) <b>b6</b> ; Jansen, Kathrin	
<b>b6</b> Kurilla, Michael G (NIH) <b>b6</b> ; Lowy, Douglas R (NIH)	
<b>b6</b> ; Young, John <b>b6</b> ; Freire, Maria C (NIH) <u>b6</u> Taba	ık,
Lawrence A (NIH) <b>b6</b> Lane, Henry C (NIH) <b>b6</b> Parker, Ashley S (NIH)	
<b>b6</b> ; Anderson, James M (NIH) <b>b6</b> ; Austin, Christopher P (NIH)	
b6 Wolinetz, Carrie D (NIH) b6	
Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group	

Dear ACTIV Executive Committee Members:

Please see the attached letter from the ACTIV Therapeutics-Clinical Working Group received this morning, for consideration on tomorrow morning's Executive Committee teleconference. While we expect the proposals contained herein will be one major topic of discussion, the purpose of the meeting is to hear from all of the Working Group cochairs (copied on this note) regarding what is working and where they may be facing challenges in ACTIV, and jointly discuss strategy moving forward.

From: Adam, Stacey (FNIH)	[T] <b>b6</b>			
Sent: Tuesday, May 12, 202	0 9:52 AM			
To: Wholley, David (FNIH) [7	[] b6	r-		
Cc: Read, Sarah (NIH/NIAID)	[E <b>b</b> 6	; Eric Hughes	b6	; Carlos O Garner
b6	; Judy Currier	b6	; Keith Gottesd	iener
b6	; Amanda Pepperco	orn	b6	; Stein, Peter (FDA/CDER)
b6	Higgs, Elizabeth (NIH/NI	AID) [E]	<b>b6</b> el	kim@deloitte.com
Subject: Letter to the ACTIV	Executive Committee fro	nm the Theraneut	ics-Clinical Workin	ng Group

Hi David,

Please find attached a letter from the Therapeutics-Clinical Working Group to the ACTIV Executive Committee for their consideration. Overall, the letter is meant to relate some broad challenges and issues that the Therapeutics-Clinical group thinks the ACTIV PPP is facing, as well as some very specific requests for assistance from the ACTIV EC for our team.

Please relay this to the ACTIV EC for their review. Our group would welcome any feedback they have.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

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From:	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS								
Sent:	5/15/2020 1:38:44 AM								
То:	Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group								
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]								
Subject:	RE: Woodcock summary of current trials								
Ah! Thanks!	It would've been nice to include this slide in our set for Moncef but it's too premature.								
I'm sending	you slides shortly.								
Thanks, Ashley									
	ley, David (FNIH) [T]								
	day, May 14, 2020 9:25 PM Ashley (NIH/OD) [E] <b>b6</b>								
	Ashley (NIH/OD) [E]   <b>b6</b> /: Woodcock summary of current trials								
	ne earlier about the list of 21 mAb companies Janet was referring to. See slide 8 from this deck FC Tuesday, think that is it.								
	s, Francis (NIH/OD) [E] <b>b6</b>								
	ay, May 12, 2020 9:43 PM  awrence (NIH/OD) [F] <b>b6</b> b: Wholley David (FNIH) [T] <b>b6</b> Austin								
-	awtence (1111) by [2], / tastin,								
James (NIH/	, and the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of								
(FNIH) [T]	OD) [E] <b>b6</b> Parker, Ashley (NIH/OD) [E] <b>b6</b> Freire, Maria <b>b6</b>								
·	oodcock summary of current trials								
•									
Interesting	inventory from Janet								
From: Wood									
	ay, May 12, 2020 9:38 PM								
	Francis (NIH/OD) [E] < b6								
Subject: RE:	Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group								
Yes you can	share. It's a bit out of date. As I said I'm doing a deeper dive on convalescent plasma and the neutralizing								
•	ould have soon. Need to fill in detail of all planned DOD and NIH studies. Should get to that this week. Jw								
	' ·								
Erom: Collin	ns, Francis (NIH/OD) [E] <b>b6</b>								
	12, 2020 at 8:48:22 PM EDT								
To: Woodco	i								
	Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group								
Hi Janet,									

share with ACTIV leadership? Francis b6 From: Woodcock, Janet Sent: Tuesday, May 12, 2020 5:01 PM b6 To: Collins, Francis (NIH/OD) [E] Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, May 12, 2020 1:31 PM To: Woodcock, Janet Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group if you can. Otherwise after 7 pm is good 5 pm? b6 From: Woodcock, Janet Sent: Tuesday, May 12, 2020 1:08 PM To: Collins, Francis (NIH/OD) [E] Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group No have to brief higher ups. Later better. Jwv From: Collins, Francis (NIH/OD) [E] b6 Date: May 12, 2020 at 12:49:32 PM EDT **To:** Woodcock, Janet ₹ Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group Yes, I would like that. Can you do 3:30? From: Woodcock, Janet Sent: Tuesday, May 12, 2020 11:28 AM To: Collins, Francis (NIH/OD) [E] Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group Can we discuss before tomorrow? jw From: Wholley, David (FNIH) [T] < Sent: Tuesday, May 12, 2020 10:46 AM To: Collins, Francis S (NIH) b6 ..♭; Stoffels, Paul [JJCUS] ﴿ ; Fauci, Anthony S (NIH) 🗄 Gibbons, Gary H (NIH) Woodcock, Janet **b6** b6 ; Pao, William Dolsten, Mikael b6 b6 }; Desrosiers, Betsy Hughes, Cc: Colvis, Christine M (NIH) Eric Read, Sarah W (NIH) Jansen, Kathrin b6

b6

Kurilla, Michael G (NIH)

I just got to this e-mail (it's been that kind of day). Wow, there is a LOT of useful information here. May I

Lowy, Douglas R (NIH)

b6	_}; Young, John [	b6	Freire,	Maria C (NIH) ₹	b6	; Tabak,
Lawrence A (NIH) {	b6	>; Lane, Henry C (N	IH) ╡	b6	Parker, Ashley S	(NIH)
h6	; Anderson, Jame	es M (NIH) <	b6	Austin,	Christopher P (N	IIH)
DU	Wolinetz, Carrie	D (NIH)	6			

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David

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b6	; Jud	y Currier		b6		Keith Gottesdie	ner	
b6	; Amanda Peppercorn <			4	<b>b6</b> ; Stein,		Peter (FDA/CDER)	
b6	; Higgs	, Elizabetł	n (NIH/NIAID)	) [E] {	b6	; elkir	n@delc	<u>iitte.com</u>
Subject: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group								

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